CV 2015 09 2258



**IN THE COURT OF COMMON PLEAS**
**BUTLER COUNTY, OHIO**
**CIVIL DIVISION**

**KATHY JILL HERSLEY**
505 East Main Street
Greensburg, IN 47240

**CASE:**

Judge:

**Plaintiff,**

v.

**COMPLAINT**
**& JURY DEMAND**

**ABUBAKAR ATIQ DURRANI, M.D.**
Pakistan
(Served via Hague
Convention)

And

**CENTER FOR ADVANCED SPINE TECHNOLOGIES, INC.**
(Served via Hague
Convention)

And

**CHRIST HOSPITAL**
2139 Auburn Avenue
Cincinnati, Ohio 45219
Serve:
CT Corporation
System 1300 East
Ninth Steel
Cleveland, Ohio
441144

**Defendants.**

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Comes now Plaintiff, Kathy Hersley, and files this Complaint and jury demand and states as follows:

1. At all times relevant, Plaintiff was a resident of and domiciled in the State of Indiana.

2. At all times relevant, Defendant Dr. Abubakar Atiq Durrani (hereinafter "Dr.

Durrani") was licensed to and did in fact practice medicine in the State of Ohio.

3. At all times relevant, Center for Advanced Spine Technologies, Inc. (hereinafter "CAST"), was licensed to and did in fact perform medical services in the State of Ohio and was and is a corporation authorized to transact business in the State of Ohio and Kentucky.

4. At all times relevant, Christ Hospital, LLC (hereinafter "Christ Hospital"), was a limited liability company authorized to transact business and perform medical services in the State of Ohio and operate under the trade name Christ Hospital.

5. At all times relevant herein, Christ Medical Center, Inc., aka Christ Hospital held itself out to the public, and specifically to Plaintiff, as a hospital providing competent and qualified medical and nursing services, care and treatment by and through its physicians, physicians in training, residents, nurses, agents, ostensible agents, servants and/or employees.

6. The amount in controversy exceeds the jurisdictional threshold of this Comi.

7. The subject matter of the Complaint arises out of medical treatment by Defendants in Butler County, Ohio. This Court is thus the proper venue to grant Plaintiff the relief sought.

8. This case was previously set for trial and Plaintiff's 41(A) Voluntarily Dismissed this case and are now re-filing this case.

## FACTUAL ALLEGATIONS OF PLAINTIFF

9. Plaintiff first met Dr. Durrani when her daughter was a patient of his at Cincinnati Children's Hospital in early 2006.

10. At the time, Plaintiff was experiencing ongoing sharp pains in her lower back.

11. Plaintiff asked Dr. Durrani to review her MRI results, after which review Dr. Durrani told the Plaintiff that several of her vertebrae were causing the Plaintiff pain by making contact with each other. Dr. Durrani immediately recommended surgery.

12. Dr. Durrani represented to the Plaintiff that he "could fix [her]" and that following the surgery he recommended she would be pain free.

13. On February 28, 2007, Dr. Durrani performed surgery on the Plaintiff consisting of a spinal fusion with installation of hardware from 15-SI at Christ Hospital.

14. Upon information and belief, Dr. Durrani used Infuse/BMP-2 or Puregen "off-label" in this surgery without Plaintiffs knowledge or consent, causing harm.

15. Afterwards, Plaintiff attended postoperative care appointments with CAST at their West Chester office.

16. Since the surgery on February 28, 2007, Plaintiff has been in constant pain and is unable to find comfort. She has lost the majority of what flexibility she previously enjoyed, and now has a hard time bending, sitting, standing, and laying for any significant period of time.

17. Dr. Durrani saw Plaintiff only one time since her February surgery, at which time she received a shot for her pain and was referred out to a pain specialist.

18. Plaintiff continues to suffer the same pain she had prior to her February surgery. In addition she now has pain in her hips and instability in her lower limbs, as well as pain and tenderness around the scars from her surgery.

19. Upon information and belief, Dr. Durrani used Infuse/BMP-2 "off-label," without Plaintiff's knowledge or consent, causing Plaintiff harm.

20. The use of BMP-2 increases a person's chance of cancer by 3.5%

21. Due to the unnecessary surgeries Dr. Durrani performed, Plaintiff has a 3.5% increased chance of cancer because of the use of BMP-2.

22. As a direct and proximate result of the use and implementation of Infuse/BMP-2 Plaintiff has incurred a 3.5% increase in the risk of Cancer. As a result Plaintiff has an increased fear of Cancer.

23. Upon information and belief, the surgery performed by Dr. Durrani was medically unnecessary and improperly performed.

24. As a direct and proximate result of this surgery and Dr. Durrani's negligence, the Plaintiff has suffered harm.

25. Plaintiff did not become aware of Dr. Durrani's use of Infuse/BMP-2 until legal counsel reviewed Plaintiffs bills.

26. Defendants fraudulently induced Plaintiff and her insurance company to pay for the surgery.

27. West Chester/UC Health made more money from surgical patients than medical patients. Dr. Durrani was a spine surgeon.

28. West Chester/UC Health made more money from more surgical procedures and more diagnostic tests and therapeutic procedures of any kind. Dr. Durrani ordered significant unnecessary diagnostic tests and procedures for his patients and the Defendants knew this fact.

29. Complex cases made West Chester/UC Health more money than simple ones. Dr. Durrani had complex cases.

30. There have been serious consequences since orthopedic device companies began sending sales representatives to the operating room of hospitals as they did and do to West Chester/UC Health.

31. The sales representatives assist the back table with the instruments, technique and managed inventory. This has allowed the hospitals to allow their staff to not know specifics about cases and orthopedic systems. This has also allowed the hospitals to avoid the cost of training their staffs for what the sales representatives do. This all applies to West Chester/UC Health

32. The sales representative adds approximately 40% to the cost of the implant and increases implant usage to 30% at West Chester/UC Health.

33. West Chester/UC Health failed to report a single incident of any kind involving Dr. Durrani to the National Practitioner Data Bank and any other reporting agency including the Ohio Medical Board despite there being countless required reports.

34. According to HRSA Data, 42% of hospitals have never made a single report to NPDB.

35. With respect to Dr. Durrani, West Chester/UC Health did not follow their written medical staff policies and procedures under their professional practice evaluation policy.

36. West Chester/UC Health failed to follow the triggers for peer review from January 2009 through May 2013.

37. Unknown Defendants include all Members of the Executive Committee, Credentialing Committee and Peer Review from 2009 through 2013.

38. Defendants have refused to produce through discovery the members of West Chester's Medical Executive Committee, Credentialing Committee and Peer Review Committee from 2009 through 2013.

39. West Chester/UC Health and the Defendants allowed Dr. Durrani from at least August 1, 2010 to October 5, 2010 to perform surgeries at West Chester while suspended.

Over 30 patients had surgeries during this time period. This intentional egregious conduct is appalling and represents fraud in the concealment. None of these 30 plus patients would have allowed Dr. Durrani to perform their surgery had they known Dr. Durrani was suspended.

40. West Chester/UC Health and Defendants bragged about and still brag about their spine surgery capabilities.

41. West Chester/UC Health failed to comply with their Medical Staff Bylaws which include:

a) Bylaws

b) Credentialing Plan

c) Rules and Regulations

42. The list of negligent acts, intentional acts and fraudulent acts by Dr. Durrani known to the hospital management, administration and board members including these Defendants include:

1) Dr. Durrani was the #1 money making doctor for West Chester.

2) West Chester planned to lease Dr. Durrani the fourth floor of the hospital for CAST physical therapy.

3) According to Paula Hawk, West Chester and Dr. Durrani were "partners in crime."

4) West Chester allowed three days of blocked surgery time and allowed more than one surgery at a time.

5) West Chester ignored their Medical Executive Committee bylaws when it came to credentialing and retaining Dr. Durrani.

6) West Chester West Chester/UC Health knew BMP-2 was being used improperly by Dr. Durrani including in minors, non-approved locations in the spine and in patients with cancer risks.

7) West Chester/UC Health knew Dr. Durrani was doing extensive multiple surgeries on patients.

8) West Chester/UC Health knew of Dr. Durrani's issues at other issues at hospitals before his application of privileges at West Chester.

9) West Chester/UC Health knew about the "Shanti Shuffle" which is an expression to describe Dr. Shanti, Dr. Durrani's employee spine surgeon, performing spine surgeries for Dr. Durrani without the consent of the patient.

10) West Chester/UC Health knew about "emergency" add on issue where Dr. Durrani would claim a surgery was an emergency to add it on to an existing schedule.

11) West Chester/UC Health knew PureGen was being used improperly by Dr. Durrani including that was never approved for human use and they bought it from Dr. Durrani.

12) West Chester/UC Health knew Dr. Durrani was the biggest revenue generator.

13) West Chester/UC Health knew Dr. Durrani would perform multiple surgeries at the same time in the OR.

14) West Chester/UC Health knew Dr. Durrani was not dictating OR reports or dictating them extremely late, often times up to six months.

15) West Chester/UC Health knew Dr. Durrani's patients had extended anesthesia waiting for surgery.

16) West Chester/UC Health marketed themselves as a world leader in spine surgery.

17) West Chester/UC Health knew Dr. Durrani was "over-utilizing."

18) The officers and administrators in depositions have admitted West Chester/UC Health knew of the issues involving Dr. Durrani.

19) West Chester/UC Health knew Dr. Durrani was not obtaining proper informed consents from his patients.

20) West Chester/UC Health knew Dr. Durrani dictated discharge summaries late and sometimes not at all.

21) West Chester/UC Health knew they were not following their bylaws, rules and policies in their supervision of Dr. Durrani.

22) West Chester/UC Health knew Dr. Durrani was abusive to staff.

23) West Chester/UC Health knew Dr. Durrani was "sloppy" in surgery.

24) West Chester/UC Health knew staff and medical staff would lie regarding Dr. Durrani issues.

25) West Chester/UC Health forced silence upon staff and medical staff.

26) West Chester/UC Health tracked BMP-2 use by Dr. Durrani to calculate their profits from its use.

27) West Chester/UC Health knew Dr. Durrani performed surgeries too late into night to the detriment of patient safety.

28) West Chester/UC Health knew Dr. Durrani's use of improper hardware in spinal surgeries.

29) West Chester/UC Health knew Dr. Durrani sometimes marketed himself as a neurosurgeon to patients.

30) West Chester/UC Health knew Dr. Durrani performed procedures beyond his scope of practice and training.

31) West Chester/UC Health knew Dr. Durrani performed surgeries with inadequate training.

32) West Chester/UC Health knew Dr. Durrani used "cut and paste" in his OR reports.

33) West Chester/UC Health knew Dr. Durrani engaged in improper financial relationships with orthopaedic product vendors.

34) West Chester/UC Health knew Dr. Durrani had the lack of attention to detail as required of a spinal surgeon.

35) West Chester/UC Health knew multiple Dr. Durrani patients suffered from improper VATS procedures, resulting in various reactive airway diseases postoperatively.

36) West Chester/UC Health knew they did not do proper credentialing procedures of Dr. Durrani prior to privileging him as a surgeon.

37) West Chester/UC Health knew Elizabeth Garrett (physician's assistant) was present and active in the OR as an assistant surgeon without the proper approval.

38) West Chester/UC Health allowed and promoted Dr. Durrani to give seminars knowing he misrepresented his status at Children's Hospital and University Hospital.

39) West Chester/UC Health knew Dr. Durrani had an improper personal relationship with Elizabeth Garrett.

40) West Chester/UC Health knew that the required tracking paperwork of BMP-2 and PureGen was not routinely completed in the OR.

41) West Chester/UC Health knew Dr. Durrani's patients were having anesthesia related complications intraoperatively and postoperatively, and did not disclose it to patients.

42) West Chester/UC Health knew Dr. Durrani failed to disclose to patients and family medical problems encountered during surgery.

43) West Chester/UC Health knew Dr. Durrani was creating health care billing fraud and they too committed billing fraud.

44) West Chester/UC Health knew Dr. Durrani handpicked patients with optimal health insurance for unnecessary surgeries to profit himself and the hospital.

45) West Chester/UC Health knew Dr. Durrani often did not contact his patient's primary care practitioner for in-patient hospital follow up appointments, and instead picked West Chester staff to cover maximize profit, and not have to disclose his wrongdoings.

43. The hospital's management administration and board members, including the Defendants, knew of the improper use of BMP-2 and PureGen by not only Dr. Durrani, but other surgeons. This Complaint contains detailed sections pertaining to these two substances.

44. There were over 185 BMP-2 victims and over 84 PureGen victims at West Chester/UC Health, all Dr. Durrani patients. There are hundreds and even probably over a thousand or more past patients of West Chester/UC Health who have no idea they have BMP-2 or PureGen in their spines and they are encountering health issues they have no idea could be caused by BMP-2 or PureGen. Two separate class actions on this issue will be filed simultaneous with this lawsuit.

45. The Annual Reports of UC Health reflect the bragging by the management, administration and board, including Defendants, of West Chester's financial performance and spine awards with full knowledge of the false information contained in them including over $4 million in fraudulent Medicaid and Medicare billings. The one for the Fiscal year ended June 30, 2013 is the last one applicable to Dr. Durrani, his last year at West Chester.

## MORE SPECIFIC ALLEGATIONS BASED UPON DISCOVERY AND DEPOSITION TESTIMONY

46. Krissy Probst was Dr. Durrani's professional and personal assistant handling professional, academic, travel, surgery scheduling, his journals, his Boards, his credentialing, his personal affairs and his bills.

47. Krissy Probst worked as Dr. Durrani's assistant for three years at Children's Hospital from 2006, 2007, and 2008.

48. Krissy Probst reported Dr. Durrani to Sandy Singleton, the Business Director at Children's for his having an affair with Jamie Moor, his physician assistant.

49. Krissy Probst resigned in 2008 from Dr. Durrani and remained working for three other surgeons in the Orthopedic Department.

50. Krissy Probst worked in the Orthopedic Department for eleven years from 2002-2013. She retired in May, 2013.

51. Krissy Probst confirmed Dr. Durrani claims being a Prince, when he is not.

52. According to Krissy Probst, Dr. Crawford, an icon in pediatric orthopedics treated Dr. Durrani "like a son."

53. According to Krissy Probst, Dr. Crawford, Chief of Orthopedics at Children's unconditionally supported Dr. Durrani no matter the issues and problems Dr. Durrani faced.

54. Dr. Durrani's patient care at Children's Hospital dropped off considerably after Jamie Moor became his physician assistant and they began their affair.

55. Dr. Durrani was the only orthopedic spine surgeon at Children's who would perform a dangerous high volume of surgeries.

56. At Children's, Dr. Durrani would begin a surgery, leave and have fellows and residents complete a surgery or do the full surgery while he was in his office with Jamie Moor, his physician assistant for four or five hours.

57. Children's Board and administration knew about Dr. Durrani doing too many surgeries and not properly doing the surgeries. They did nothing.

58. Dr. Durrani argued to Children's administration when they complained to him that he made them money so Children's tolerated him and allowed him to do what he wanted.

59. Dr. Durrani, when told by Children's that Jamie Moor had to leave, told Children's that he would leave too.

60. Dr. Agabagi would do one spine patient a day at Children's because it takes normally eight hours for a full fusion.

61. Dr. Durrani would schedule two to three spine surgeries a day at Children's.

62. Dr. Durrani would repeatedly have the Business Director, Sandy Singleton, or OR Director allow him to add surgeries claiming they were emergencies when they were not.

63. Dr. Durrani would leave a spine surgery patient for four or five hours in the surgery suite under the care of fellows or residents, unsupervised and sit in his office and check on the surgery as he pleased.

64. Dr. Peter Stern did not like Dr. Durrani while Dr. Durrani was at Children's because he knew all about his patient safety risk issues. Yet, Dr. Stern supported, aided and abetted Dr. Durrani's arrival at West Chester. It defies comprehension, but was for one of the world's oldest motives—greed of money.

65. There is also a Dr. Peter Sturm, an orthopedic at Children's who also had no use for Dr. Durrani.

66. Dr. Durrani chose his own codes for Children's billing which he manipulated with the full knowledge of Children's Board and management.

67. Dr. Durrani was dating and living with Beth Garrett, a nursing school drop-out, with the full knowledge of his wife Shazia.

68. Dr. Durrani was close with David Rattigan until David Rattigan pursued Jamie Moor and Dr. Durrani would not allow David Rattigan in the OR at Children's for a long time.

69. Dr. Durrani, while claiming to have riches, does not. Dr. Durrani's wife's family paid for Dr. Durrani's education and it is her family with the significant wealth.

70. Medtronics paid for Dr. Durrani's trips and paid him $10,000 fees for speaking or simply showing up at a spine conference.

71. Krissy Probst's business director told her to save all Dr. Durrani related documents and information and she did.

72. While doing research at Children's, Dr. Durrani would misstate facts regarding his research. Children's knew he did this.

73. Dr. Durrani ended on such bad terms with Children's Hospital he was not allowed on the premises after his departure in December 2008, yet he performed a spine surgery there in February 2009.

74. Eric J. Wall, MD was the Director of Surgical Services Division of Pediatric Orthopedic Surgery when Dr. Durrani left Children's.

75. Sandy Singleton, MBA was the Senior Business Director of Surgical Services Division of Pediatric Orthopedic Surgery when Dr. Durrani left Children's.

76. On information and belief, Dr. Durrani used his relationships with Children's officials to purge his Children's file of all patient safety and legal issues which had occurred as part of his departure "deal" which Defendants hide with privilege.

77. Defendants committed fraud by misrepresenting Dr. Durrani's reputation. Defendant knew he was doing unnecessary spine surgeries and concealing them from Plaintiffs. With the intent to mislead Plaintiffs, and knowing Plaintiffs would rely upon the misrepresentations and concealment, Defendant caused harm to Plaintiffs. Defendant knew their false information regarding Dr. Durrani was material to Plaintiffs decision making in choosing Dr. Durrani as a surgeon, allowing him to perform surgery, following his recommendation and being trusting to have their procedures at Defendant hospitals.

78. Dr. Durrani's CAST website states in part: "The entire focus at CAST is on the patient. From the ease in getting in to see a physician…to wellness, therapy and treatment programs that can help patients avoid surgery…to minimally invasive techniques if surgery is necessary…to our remarkable facility and one-site convenience. It's time patients have the level of preventive care and advanced treatment we offer. Atiq Durrani, MD- Founder of CAST." As shown and will be shown, this is a material misrepresentation which is false

relied upon by Dr. Durrani's patients including Plaintiffs to allow Dr. Durrani to perform unnecessary surgeries on Plaintiffs.

79. Gerry Goodman worked under a Corporate Integrity Agreement in 2010 at West Chester/UC Health.

80. Gerry Goodman, from August to November 2010, while serving as the interim director of OR nursing at West Chester Medical Center, complained to administration including Mitch McCrate about Dr. Durrani's deviations and violations of law, policies, bylaws, rules and regulations which were effecting patient care, including Plaintiffs.

81. Mitch McCrate told Gerry Goodman West Chester/UC Health wasn't concerned because "the hospital had state funding and therefore was not held to qui tam rules."

82. Gerry Goodman told Mitch McCrate, General Counsel; Jack Talbot, HR; George Caralis, COO and Kevin Joseph, MD, President; that Dr. Durrani had a "partner" who had not received provider status and Dr. Durrani was billing his "partner" under Dr. Durrani's provider number, something which was illegal.

83. The "partner" was Dr. Shanti.

84. Dr. Durrani and Dr. Shanti would do three or four cases simultaneously and bill them simultaneously.

85. Gerry Goodman told McCrate, Talbot, Caralis and Joseph she could not work in a place which condones illegal practices. They asked her to ignore them. She refused.

86. Dr. Durrani, according to Gerry Goodman, did whatever he wanted in the OR and knew he could get away with it including being treated like a king by the vendors.

87. Vendors such as Medtronic representatives were allowed in the OR after going through the preapproved process they must go through. David Rattigan, Dr. Durrani's primary vendor, worked at Bahler peddling Medtronic products.

88. Dr. Durrani was abusive to his and West Chester/UC Health staff. This was tolerated by West Chester/UC Health and effected patient care including that of Plaintiffs.

89. Dr. Durrani never cared about others schedules or the West Chester/UC Health OR schedule.

90. Dr. Durrani declared every surgery an emergency to ignore schedules.

91. Dr. Durrani received two full days and two half days of block time at West Chester/UC Health. It was never enough time for his over utilization.

92. When Gerry Goodman would say no to a Dr. Durrani scheduling request, Dr. Durrani would contact West Chester/UC Health administration and she would be overridden.

93. Gerry Goodman had skill, knowledge and experience to recognize a "Dr. Durrani" because she had been involved in the outing of another over-utilizer and unnecessary procedure surgeon performing cardiac catherizations.

94. Spine surgeons usually do one or two a day, possibly three surgeries a day if an emergency.

95. Dr. Durrani would often do four, five and even six surgeries.

96. Dr. Durrani and Dr. Shanti would walk from surgical room to surgical room with all the spine patients "open" for an extended time past the standards of care.

97. On at least two occasions, Dr. Durrani patients were open for in excess of an hour waiting for him to come into the case.

98. When Gerry Goodman would complain to Dr. Durrani about patients being under anesthesia and the operative site open for long periods of time, Dr. Durrani would claim "we are covering anesthesia with antibiotics."

99. When Dr. Durrani performed with Dr. Shanti these multiple simultaneous procedures, they were billed as if he was the attending surgeon in all three surgeries.

100. The Dr. Shanti and Dr. Durrani "open and switch" to do the surgery, we have labeled the "Shanti Shuffle."

101. The Shanti Shuffle is not the normal. Shanti did not assist, he replaced.

102. Gerry Goodman complained to risk management repeatedly to no avail of the Shanti Shuffle.

103. When Gerry Goodman pointed out to risk management, Jill Stegman and David Schwallie that Dr. Durrani had all the "red flags" from over utilization and being bounced out of other area hospitals, they responded "how did you know." Gerry Goodman knew because anyone in hospital administration and management in the tristate in 2008 to 2013 knew. Dr. Durrani was no secret.

104. Jill Stegman and David Schwallie admitted to Gerry Goodman they knew about Dr. Durrani's over utilization, being "bounced out" of other hospitals and all the issues going on with him with the OR, but West Chester needed Dr. Durrani's numbers.

105. When Gerry Goodman complained to George Caralis about Dr. Durrani, he told Gerry Goodman to "keep your mouth shut and go back to work because you are just an interim."

106. George Caralis told Gerry Goodman that West Chester/UC Health needed Dr. Durrani surgeries and admissions and therefore they were not going to stop him.

107. Jill Stegman and David Schwallie informed Gerry Goodman they would get back with her about Dr. Durrani in a few days. They never did.

108. After Gerry Goodman was blown off by David Schwallie and Jill Stegman, she decided to leave her work assignment at West Chester/UC Health.

109. Gerry Goodman checked the written consents of BMP-2 patients including Plaintiffs which Dr. Durrani, CAST and West Chester/UC Health had them sign and confirmed they did not provide consent to BMP-2.

110. Gerry Goodman reported on the lack of consent for BMP-2 also to Schwallie, Stegman, Joseph, Caralis, Talbot and McCrate and they ignored her.

111. Gerry Goodman verified there was nothing in the patients' charts, including Plaintiffs' charts, reflecting they were informed of the risks of off label use of BMP-2.

112. Upon hearing her repeated complaints about Dr. Durrani, George Caralis told Gerry Goodman she was just an "emotional female."

113. Gerry Goodman reported to no avail patient safety issues caused by the OR staff working from 7 AM to midnight on Dr. Durrani patients. Fatigue caused deviations in standard of care by West Chester/UC Health staff's including in Plaintiffs.

114. No action was taken by West Chester/UC Health's board or management to correct the informed consent issue on BMP-2. The time period of Gerry Goodman's warning and complaints were fall 2010. Plaintiffs' claims arise from January 1, 2009 through May 2013. At least, according to Gerry Goodman's interim service, any Plaintiff having BMP-2 placed after the fall of 2010 at West Chester/UC Health is a further tragedy because the Board, administration and management can't obey notice and they allowed Dr. Durrani to continue placing BMP-2 at will. Why? Money. Despite having full knowledge of the issue, West Chester/UC Health's board and management allowed patients including Plaintiffs to have BMP-2 placed in them by Dr. Durrani at their facility without warning them, with full knowledge they were not warned.

115. Gerry Goodman knew anesthesia charged per the minute or in fifteen minute increments and she considered it a fraud to bill for unnecessary anesthesia when patients were "open" longer than necessary.

116. Dr. Durrani would contact Medtronics and other vendors directly, they would bring into the OR what Dr. Durrani requested and then invoice West Chester/UC Health.

117. During surgeries, Medtronics and other vendors would want to up sell products.

118. This process was distracting to the OR staff and affected patient care.

119. Dr. Durrani told Gerry Goodman Dr. Shanti had privileges, but wasn't yet on all the insurance panels.

120. Gerry Goodman asked Dr. Durrani: "Which panel so he's not doing those cases?"

121. Dr. Durrani told Gerry Goodman in response: "We're doing these procedures together. They're billed under my name."

122. Gerry Goodman witnessed one case where Dr. Durrani was never in the room at all, just Dr. Shanti. Yet, Dr. Durrani claimed the procedure.

123. Gerry Goodman confronted Dr. Shanti and he simply stated: "Dr. Durrani and I are co-surgeons."

124. Gerry Goodman verified Dr. Shanti was not on the written informed consents for these procedures.

125. Kevin Joseph, MD, and President of West Chester Medical Center, knew everything Gerry Goodman complained about because either she told him or George Caralis told him. Caralis told her he told him.

126. Dr. Durrani had no supervision at all at West Chester/UC Health.

127. When Gerry Goodman attempted to supervise him, the West Chester/UC Health management as described here rebuked her.

128. Gerry Goodman also informed Mitch McCrate, Jill Stegman, David Schwallie, George Caralis and Kevin Joseph, MD, that Dr. Durrani's high volume of fusions of the spine was not usual practice. They ignored these concerns.

129. West Chester/UC Health's board and management, did not provide proper supervision of Dr. Durrani as required through the surgery and orthopedic departments. (See Bylaws section to follow)

130. Gerry Goodman also spoke to the Chief of Surgery at West Chester Medical Center about Dr. Durrani to no avail.

131. The West Chester/UC Health manager who did analytics and kept records sent to Gerry Goodman at her request, months' worth of their BMP tracking. She kept it and still has it.

132. West Chester/UC Health has previously denied tracking BMP-2. They lied. They tracked it to analyze the profit. They liked the profit. They encouraged Dr. Durrani to place all the BMP-2 he could.

133. Based upon Gerry Goodman's documentation, Plaintiffs have requested and expect to receive all BMP-2 tracking as evidence of Plaintiffs BMP-2 claims.

134. West Chester/UC Health's board and management increased the cost of the surgeries of Plaintiffs and patients by using BMP-2 infuse.

135. Dr. Durrani would also sign operative reports he never dictated with the full knowledge of West Chester/UC Health's board and management. This is yet another practice Gerry Goodman complained about.

136. Dr. Shanti dictated operative reports he never signed with the full knowledge of West Chester/UC Health's board and management. They knew because Gerry Goodman complained.

137. Orthopedics and spine surgeries are some of the highest sources of income for a hospital and were too for West Chester/UC Health.

138. In the spring of 2013, Dr. Peter Stern told Dr. Angelo Colosimo, UC Orthopedic Surgeon that West Chester/UC Health "knew all about Dr. Durrani's issues before he came to us and after he came to us, but we needed the money."

139. The billings for Dr. Durrani surgeries were sent to Plaintiffs at their homes with requests for payment.

140. Plaintiffs were required to make payments of uncovered medical bills to Dr. Durrani and CAST.

141. Dr. Durrani produced, distributed and utilized a video of a lecture involving his EDS patients to solicit more patients.

142. Unbeknownst to his EDS patients, Dr. Durrani was doing experiments on these EDS patients including many of the Plaintiffs without informing them they were part of an

experiment. This too violated West Chester Medical Staff Bylaws as revealed in a later section.

143. Dr. Durrani claims in his EDS video a 95% success rate with the C1-C2 operations and only one of the twenty-five claimed they would not have the surgery again.

144. The undersigned counsel represents 20 of these 25 persons and not one would have the surgery again. They are Plaintiffs.

145. Dr. Tayeb was an employee of Dr. Durrani from 2009 to 2013. Counsel has interviewed him extensively.

146. Dr. Tayeb will testify that Dr. Durrani improperly selected patients for surgery, and then recommended surgery, including patients with EDS that were not proper candidates for surgery including many of the Plaintiffs.

147. Dr. Tayeb will testify that improper business practices occurred at CAST, including Dr. Durrani recommending surgeries that were medically unnecessary including the Plaintiffs.

148. Dr. Tayeb will testify that Dr. Durrani made decisions to place wealth and status over the well-being of his patients including Plaintiffs.

149. Dr. Tayeb, Dr. Durrani's pain management doctor for a time at CAST, reports that Dr. Durrani's misuse of BMP-2 resulted in bony overgrowth, where "it's like a big block of bone back there where you can't even stick a needle there anymore" and patients, including Plaintiffs would develop neuropathic pain.

150. Dr. Tayeb could not reach the nerve in many of the BMP-2 patients to even treat with injections.

151. Dr. Tayeb would engage Dr. Durrani in shouting matches at CAST over patient care that others witnessed.

152. According to Dr. Tayeb, Dr. Durrani would not always speak truthfully about patients having already gone through conservative care.

153. According to Dr. Tayeb, Dr. Tayeb believes West Chester knew about Dr. Durrani's prior issues.

154. According to Dr. Tayeb, surgical notes were not being done timely and there are some "clinical ramifications."

155. According to Dr. Tayeb, many times surgeries were performed in different areas than the work up.

156. According to Dr. Tayeb, patients would not understand what Dr. Durrani was doing.

157. According to Dr. Tayeb, Dr. Durrani loved to tell patients he would "fix" them.

158. According to Dr. Tayeb, Dr. Durrani told patients they would be paralyzed.

159. According to Dr. Tayeb, Dr. Durrani exaggerated the diagnosis of lumbar degenerative disc disease and stenosis.

160. According to Dr. Tayeb, ER patients with back pain were referred to Dr. Durrani.

161. According to Dr. Tayeb, he heard about West Chester facing financial challenges.

162. According to Dr. Tayeb, he is of the opinion Risk Management knew about Dr. Durrani issues.

163. According to Dr. Tayeb, Paula Hawk at a meeting with Dr. Durrani, Dr. Tayeb and Brian Gibler (CEO UC Health said: "We work with Dr. Durrani. We cater to Dr. Durrani, you know, to point where we want to try to expedite and make everything easy for you guys to bring everything over here." "He's our partner in crime."

164. According to Dr. Tayeb, there were a suspicious high number of spine surgeries.

165. According to Dr. Tayeb, Dr. Durrani bragged in the halls he was the top money maker.

166. According to Dr. Tayeb, he's aware of at least one time four (4) surgery suites reserved at one time for Dr. Durrani.

167. According to Dr. Tayeb, West Chester advertised they were a premier spine institute.

168. According to Dr. Tayeb, there was a discussion about CAST and West Chester co-oping and Dr. Durrani wanted a "piece" of the action.

169. According to Dr. Tayeb, there were $100 a day fines for records over 30 days late. He has no idea if Dr. Durrani was fined.

170. According to Dr. Tayeb, Dr. Durrani went an entire six months—no records.

171. According to Dr. Tayeb, there were also issues of too long of days in surgery.

172. According to Dr. Tayeb, Dr. Durrani had two heart attacks and would get sick, go to ER get fluids and keep operating.

173. According to Dr. Tayeb, Dr. Tayeb believes Dr. Joseph had to have knowledge of the issues.

174. According to Dr. Tayeb, Dr. Durrani was super aggressive.

175. According to Dr. Tayeb, seen in clinic to surgery scheduling was for 30 patients 20-30% for Dr. Durrani.

176. According to Dr. Tayeb, others for 30- one or two scheduled.

177. According to Dr. Tayeb, Dr. Durrani would schedule surgeries without looking at MRI or ordering one.

178. According to Dr. Tayeb pertaining to Dr. Durrani, "I think it was just everything that was walking needed to be cut on in some way, shape or form whether it was necessary or not."

179. According to Dr. Tayeb, Defendants held discussions with Dr. Durrani regarding using 4th floor of hospital for CAST rehab.

180. According to Dr. Tayeb, lack of documentation effects patient care and West Chester responsible.

181. According to Dr. Tayeb, he heard the "paralyze" and "severe stenosis" to patients from Dr. Durrani a lot.

182. Elizabeth Dean was employed at West Chester Medical Center before they opened the doors for business.

183. Elizabeth Dean was one of the original patient access representatives at West Chester Medical Center, which is now West Chester Hospital, beginning employment in February 2008 to July 2010.

184. Elizabeth Dean had many responsibilities within the hospital including admitting Dr. Durrani patients and completing financial reports for the West Chester/UC Health CFO, Mike Jeffers.

185. Elizabeth Dean was also included in most corporate meetings where discussions took place over the mass injections performed by Dr. Durrani in the testing area of the hospital and she also was the actual patient access representative who registered and spoke with all the Durrani patients.

186. According to Elizabeth Dean, before Dr. Durrani began to practice at West Chester Hospital, every area of the hospital was a "ghost town."

187. Despite being a new hospital, it was still not picking up revenue as it expected.

188. Elizabeth Dean was required to ask for all copays when the patients arrived, just to "keep the numbers up" as much as possible.

189. Elizabeth worked for five years as a medical biller with University Internal Medicine Associates before coming to West Chester.

190. Elizabeth Dean knew West Chester/UC Health needed money based upon her position and work at West Chester.

191. Elizabeth Dean reviewed the final numbers from CFO Mike Jeffers each month and also logged all payments received on the surgery cases including Dr. Durrani's.

192. West Chester/UC Health's board and management gave staff raises based upon the hospitals financial woes.

193. West Chester/UC Health fired the original CEO and corporate employees once the hospital was bought by UC Health, and appointed an ER physician as the new CEO, Kevin Joseph, MD.

194. Elizabeth Dean will testify that West Chester/UC Health decided to have West Chester/UC Health ran by physicians.

195. Vickie Scott worked at West Chester in the operating room during the time Dr. Durrani also worked there.

196. OR Nurses, including Vickie Scott, went to the OR management, Elaine Kunko and Denise Evans and to Risk Management, Jill Stegman, about Durrani's illegal activities, deviations in standard of care and violations of policies, bylaws, regulations and rules. No action was taken. They complained and reported the same issues Gerry Goodman reported as previously described.

197. Vickie Scott informed Elaine Kunko, OR assistant manager, about Dr. Durrani making the records appear that Dr. Durrani was doing all the procedures when they knew it was Dr. Shanti. Kunko did nothing to stop the Shanti Shuffle.

198. Scott Rimer, circulating nurse at West Chester Medical Center, spoke up and complained about Dr. Durrani at an OR meeting with OR staff and hospital administration. Not only was Scott Rimer ignored, the next day he had his supervisor standing next to him watching his every move. He was fired soon after.

199. In summary, Gerry Goodman, Vickie Scott, Scott Rimer and other OR staff members complaints to management included the number of Dr. Durrani surgeries he did a day and at a time; other surgeons performing surgeries for him without proper consent; Dr. Shanti not having proper qualifications and provider numbers; BMP-2 was tracked by the hospital despite their denials of doing so; Dr. Durrani was verbally abusive to everyone; anesthesiologists had to have patients "under" longer than they should have been; off label use of BMP-2 was not covered by informed consent; Medtronic reps would "up-sale" during

surgeries; operative reports were not timely completed; Dr. Durrani had no supervision by the hospital; keeping OR staff past the time it was safe.

200. Those Gerry Goodman, Vickie Scott, Scott Rimer and other OR staff members complained to included Mitch McCrate, Jack Talbot, George Caralis, Kevin Joseph, MD, Melissa Hemmer, Elaine Kunko, Denise Evans, Jill Stegman, and David Schwallie. All of these individuals are and/or were West Chester/UC Health management who communicated these complaints to the board. Many like Kevin Joseph, MD, President were on the board.

201. West Chester/UC Health, its board and management, also knew of Dr. Durrani's sexual harassment of OR nurses and staff and ignored it.

202. Melissa Dowler witnessed Dr. Durrani offer a nurse in the OR $10,000 for oral sex.

203. Dr. Durrani had an affair with his staff member, Beth Garrett, who dropped out of nursing school, and like his relationship with a prior physician assistant at Children's Hospital, Jamie Moor it affected patient care.

204. Dr. Durrani, by his deposition testimony, admits he relies upon his own reading of radiology. Of course, in this manner he would recommend a surgery the radiology did not support. The radiology department at West Chester, the director of radiology and all the radiologists privileged at West Chester from January 1, 2009 to June 1, 2013, knew Dr. Durrani was ignoring their radiology interpretations and did nothing to address the issue and/or were ignored when they tried to address the issue.

205. Dr. Durrani, by his deposition testimony, admits he informs the pain doctor where to inject medicine. By doing so in the wrong place, he convinced many Plaintiffs to have repeat surgeries.

206. Melissa Garrett is forty-one (41) years old, and is a pharmaceutical salesperson in Tampa, Florida. Melissa Garrett said her sister Elizabeth "Beth" Garrett who worked for Durrani/CAST.

207. Melissa Garrett contacted counsel and stated that Beth Garrett was holding herself out as a nurse, although Beth Garrett had failed out of nursing school.



208. Melissa Garrett stated that Beth Garrett had been present during surgeries by Dr. Durrani.

209. She stated that Beth Garrett had improperly assisted in surgical procedures performed by Dr. Durrani without a nursing license.

210. She stated that Beth Garrett had been improperly selling pharmaceutical products, without a license.

211. She stated that Beth Garrett was having an "affair" with Dr. Durrani, and that she was concerned after Beth Garrett brought Dr. Durrani to her son's elementary school function and that the family "freaked out" in response to Beth Garrett and Dr. Durrani's conduct during the school function.

212. Dr. Durrani prescribes a custom compound cream he sells to patients without informing them which he bills to their insurance and just sends to them.

213. On information and belief Dr. Durrani owns some interest in this compound cream in a physician owned distributorship (POD) arrangement.

214. Shauna O'Neal followed Gerry Goodman to West Chester as Director of Nursing.

215. Shauna O'Neal came from Compass Clinical Consulting group in Cincinnati.

216. Shauna O'Neal wrote a letter to Tom Daskalakis the COO of West Chester/UC Health, Kevin Joseph, MD, and the CNO in which in which she reiterated what Gerry Goodman reported regarding Dr. Durrani's OR bookings and Dr. Shanti's lack of credentials and/or privileges. She was ignored.

217. Thomas Kunkel, MD, anesthesiologist, complained to West Chester/UC Health's board and management about Dr. Durrani's high number of "add on" patients. He was ignored.

218. According to Gerry Goodman, Dr. Durrani did add on patients at the last minute and after regular business hours so there was no one to preauthorize patients or question Durrani in any way regarding the surgery.

219. Dr. Durrani always told Thomas Kunkel, MD the surgeries were emergencies.

220. At times anesthesiology demanded the Chief of Surgery to intercede to judge whether or not it was emergent.

221. Cindy Traficant was Periop Director before and after West Chester opened.

222. When UC Health took over, Julie Holt, the original CNO, quit.

223. Cindy Traficant became interim CNO.

224. Cindy Traficant had a reputation of tolerating "bad" physicians.

225. West Chester Surgery was nicknamed by staff at West Chester/UC Health the "island of misfit" doctors because they took in and tolerated any doctor no matter their ethics, including Dr. Durrani.

226. OR staff collectively reported Dr. Durrani issues to West Chester/UC Health board and management and their complaints were ignored.

227. Dr. Durrani would sometimes, because he was running behind, cancel part of a surgery or do only part of the surgery, thus requiring the patient to have another surgery, all without informing the patient the cancellation was because he was late.

228. Dr. Durrani performed 159 surgeries at West Chester Medical Center in 2009; 534 in 2010; 536 in 2011; 437 in 2012; and 157 in 2013 for a total of 1,823 surgeries.

229. West Chester/UC Health admitted in a discovery answer in the *Shell* case that for the investigation, background check and the information used to decide to grant Dr. Durrani privileges they relied upon in part:

- Dr. Durrani's education.
- Dr. Durrani's training and experience.
- Copies of his licenses and DEA numbers.

- Inquiry to the National Practitioners Data Bank.
- Evidence of required continued education.

230. West Chester/UC Health refuses to provide under a claim of privilege all persons they consulted prior to permitting Dr. Durrani privileges.

231. Dr. Durrani total **surgeries** performed as answered in a discovery in *Shell* at West Chester is as follows:

2009: 665

2010: 1908

2011: 1736

2012: 1102 (Through 9/30/12)

232. Dr. Durrani admitted as **inpatient** based as answered in a discovery answer in *Shell* at West Chester is as follows:

2009: 154

2010: 488

2011: 507

2012: 305 (Through 9/30/12)

233. Dr. Durrani admitted as outpatients based as answered in a discovery answer in *Shell* at West Chester is as follows:

2009: 13

2010: 41

2011: 45

2012: 35 (Through 9/30/12)

234. West Chester/UC Health refuses to provide under a claim of privilege their investigation to determine Dr. Durrani's fitness to practice medicine prior to permitting Dr. Durrani privileges.

235. West Chester/UC Health refuses to provide under claim of privileges, the instances where Dr. Durrani did not follow proper medical documentation protocol, policies and/or procedures at West Chester/UC Health.



236. West Chester/UC Health refuses to provide under claim of privileges, the complaints made by employees, staff or patients related to Dr. Durrani.

237. Dr. Durrani oftentimes used PureGen when performing surgeries, if this case involves PureGen, this is noted within this Plaintiff's specific factual allegations addressed earlier in this Complaint.

238. PureGen has never been approved by the FDA for any human use. It's also now off the market for any use.

239. Doctor Atiq Abubakar Durrani used the product PureGen in his capacity as a medical doctor in spines in the same manner BMP-2 was used.

240. West Chester/UC Health assisted Dr. Durrani in his use of PureGen at their facility.

241. A representative from Alphatec Spine was in the operating room during medical procedures per the Nursing Intra-op Records when Dr. Durrani used PureGen.

242. A representative from Alphatec Spine was in the operating room during medical procedures even when the Nursing Intraop Records do not indicate so.

243. Dr. Durrani was and is a paid consultant for Alphatec Spine.

244. Dr. Durrani has an ownership stake in the Alphatec Spine.

245. Dr. Durrani provided PureGen to patients who required surgery and those who did not require surgery without Plaintiffs knowledge and consent.

246. Dr. Durrani performed unnecessary surgeries using PureGen on his patients.

247. West Chester Hospital, UC Health and the Center for Advanced Spine Technologies knowingly created false medical records, bills, and cost reports that included charges for unlicensed uses of PureGen, which resulted in inflated outlier payments to be paid by the

government and other insurers using the Plaintiffs' right to make a claim; or in the alternative, causing a false cost reports.

**TRIGGERS - RETENTION**

248. With respect to Dr. Durrani, West Chester/UC Health did not follow their written medical staff policies and procedures under their professional practice evaluation policy.

249. West Chester/UC Health failed to follow the triggers for peer review from January 2009 through May 2013.

250. The following are the triggers for peer review or other actions as provided by West Chester/UC Health to the Deters Law Office in discovery in related litigation and is a list which by their own admission is not exclusive and is a list they produced after full knowledge of the items Dr. Keith Wilkey, Plaintiffs' experts, considered triggers:

A. Wrong operative procedure performed

B. Serious injury due to medical device

C. Procedure performed on wrong patient

D. Medication resulting in death

E. Delay in diagnosis

F. Autopsy not correlated with clinical diagnosis

G. Delay in treatment resulting in serious injury or death

H. Alleged abuse or neglect

I. Unexpected death

J. Surgical death

K. Mortality review

L. Unplanned second surgeon called to OR

M. MD not credentialed for procedure

N. Focus review

O. Incident reports

P. Contraindication to surgery

Q. Unintended retention of foreign object in a patient after surgery

R. Complications from procedure (i.e. readmits, infections, pneumothorax after procedure)

S. X-ray discrepancies

T. Returns to surgery

U. Transfusion not meeting criteria on order sheet

V. Change in surgery/procedure

W. Laceration/or perforation/puncture of organ during invasive procedure

X. Acute MI or CVA within 48 hours of procedure

Y. Anesthesia complications

Z. MD without timely response to ED or unit call

AA. Risk management issues

BB. Delay in treatment not resulting in serious injury and/or death

CC. Delay in diagnosis not resulting in injury or death

DD. Acute blood loss as indicated by procedure

EE. Appropriate care measures not ordered

FF. Readmission- complication of previous admission

GG. Unplanned admission following surgery

HH. 72 hours returns to ED and readmit same issue

II. Insufficient documentation

JJ. BMP-2

KK. PureGen

LL. Late dictation or no dictation of operative reports or discharge summaries

MM. False claim of spondylolisthesis

NN. False claim of stenosis or its severity

OO. Performing surgeries on patients whose health condition vitiates surgery: age, diabetes, obesity, hypertension, mental health issues, etc.

PP. Shanti Shuffle- Dr. Shanti being forced to do an entire surgery for Dr. Durrani by Dr. Durrani without the patient's knowledge.

QQ. No hospital consents or improper CAST consents

RR. Failed Hardware

SS. Performing surgery not qualified to perform

TT. Dura tear

UU. Having hardware which should be removed, which is never removed

VV. Not using the proper cage with BMP-2

WW. Ignoring radiology results

XX. Misrepresentations to primary care physicians

251. Dr. Keith Wilkey, a board certified spine expert, has reviewed over 213 patient charts at West Chester of Dr. Durrani and signed 213 affidavits of merit as required under CR10 of Ohio Rules of Procedure to file a medical malpractice case and based upon these reviews over 500 events triggers place which would have required action against Dr. Durrani by West Chester. Defendants intentionally took no action.

252. In 2008, insurance companies became much more selective in what they would authorize for payment. They started only paying for spinal surgeries that were highly indicated, meaning there was rock solid medical evidence to support their necessity for treatment of patients.

253. Certain diagnoses such as spondylolisthesis and severe spinal stenosis have good literature support for complicated lumbar fusion procedures with instrumentation, highly indicated procedures with good outcomes which result in; more pay for Durrani. Dr.

Durrani would use these extensively. The data shows Dr. Durrani falsely claimed spondylolisthesis diagnosis 95% of the time.

254. Most of the surgeries Dr. Durrani actually performed were a lesser indication; mainly degenerative disc disease with lesser amounts of spinal stenosis which insurance companies will not usually pay for the more expensive spinal fusion; less pay for Dr. Durrani. This is why Dr. Durrani would claim the conditions of spondylolisthesis.

255. Surgeons have to obtain advanced authorizations from the patient's insurance carrier prior to doing the surgery. If surgeons are requesting to do a surgery with a lesser indication, most of the time it is denied unless the requesting surgeon can convince a "peer surgeon" of the need to do the bigger surgery and demonstrate why this case is an exception to their policies. That takes time and the peer has access to the patient's whole medical record. That peer reviewer could easily have discovered the fraudulent diagnoses Durrani was claiming.

256. Beginning in 2009, Dr. Durrani lied much more often to avoid the whole process and possibility of discovery by the insurance companies.

257. Dr. Durrani didn't do his operative reports on time so as to assist his cover-up of the fraudulent diagnoses.

258. Government has given hospitals incredible power to act as the "watch" for patient's safety and well-being, but with that power comes responsibility.

259. West Chester Hospital had the duty to monitor its physicians via the peer review process and at least on paper, they had the process in place.

260. In that process, West Chester had several "triggers" established which would have resulted in an in-depth peer review. Triggers don't have to be events or behaviors that are malpractice, but are designed to be even more sensitive.

261. Most of those triggers are suggested by the government such as complications and return to surgery. However, hospitals are supposed to adjust their triggers for the individual

physicians depending on their practice type and behaviors. This is to insure that the hospital has meaningful triggers for each physician. It wouldn't make sense to monitor operative reports for an internist that doesn't operate. It would make more sense to look at his discharge summaries.

262. For Dr. Durrani, meaningful triggers would have been items tracked during the medical record review of the malpractice claims. Although complications such as hardware failure, nonunion and revision are not mandated by the government for hospital triggers, any responsibility peer review committee should have reviewed Dr. Durrani's results and adjusted the triggers for Dr. Durrani to reflect his higher than normal complication rate in these areas. Other areas tracked should have included his off-label and contraindicated use of Infuse and PureGen.

263. Defendants failed to act upon an overwhelming amount of material. There were over 591 individual triggers that were ignored by West Chester. That is overwhelming and unforgivable for a hospital to allow, given the power they had to protect their patients from harm.

264. On peer review, they are asked to identify and assist with the removal of known incompetence. A surgeon's duty on the peer review panel is to protect patients from illegal operations. Surgeons look for false and fraudulent diagnoses plus fictitious medical treatment.

265. The peer review committee is asked to sit on the committee for usually two years at a request.

266. West Chester Hospital had bylaws based upon the joint commission accreditation of healthcare organizations known as "The Joint Commission." The principles of the initial credentialing that allowed Dr. Durrani to start operating and mechanisms available to the hospital to stop him from harming other patients a basically equivalent. There are some "minor" variations between state laws but for the most part, they are the same. An example

would be the "process" called summary suspension, after it becomes clear of a physician's incompetence, the mechanism to remove him are the same everywhere. Therefore, the situation regarding West Chester and Dr. Durrani are unique only in their depth and degree to which Dr. Durrani's egregious behavior was allowed to harm patients before he was stopped only by the filing of over one hundred lawsuits.

267. The credentialing and peer review work is kept secret from the public.

268. Credentialing is a very lengthy application where 40 to 100 pages of documents are required. Each of these have to be verified by the credentialing personnel from the hospital and then a committee member is assigned to do a further background check into these applicants past work to include calling references, hospitals and training programs.

269. Within some broad limits, one can probe very deep into the past of an applicant because the applicant signs multiple disclosure agreements before the background check. This insures that if needed, the peer review can make good recommendations to the committee chairperson.

270. Given Dr. Durrani's behavior and clinical problems in Cincinnati at the time he was applying for credentials at West Chester, phone calls should have been made regarding Dr. Durrani's past work history, particularly at Children's Hospital. Another "red flag" that Dr. Durrani would have had was the fact he was not board certified by the American Academy of Orthopedic Surgeons or a member of the North American Spine Society.

271. Being board certified and a member of a specialty society is a good way for a hospital to have some external quality check for the applicant. If the applicant doesn't have those in their packet, it's a "red flag" and the reviewer for the committee has to be vigilant and do extra digging.

272. If West Chester and Defendants had called and received reports not favorable to Dr. Durrani the information would be confidential and administration could still take a chance and convince the physicians of the credentialing committee and MEC to allow the

privileging anyway. Privileging under these circumstances is usually granted by the staff with very strict terms and the physician would be on a very "short leash."

273. If this happens, the physician is put on a strict probationary period with any violation of the bylaws resulting in termination and databank report is filed.

274. Dr. Durrani was incompetent and he should have had an immediate summary suspension and a National Practitioner's Databank report should have been filed after a fair hearing confirmed the initial suspension. This report would be the only way the public would know that Dr. Durrani was found to be incompetent by his peers at West Chester. This report did not happen and the hospital administration officers, Board members and Defendants were protecting Dr. Durrani from the usual process of peer review.

275. The hospital administration has considerable control of the peer review process. They rightly claim the actual process of reviewing the patient's records and voting on the issue at hand is done by the hospital medical staff. The administration controls all the remaining variables; the physicians assigned to the committee are assigned to review the individual case, which physician is reviewed and the selecting "triggers" for the process and, the "assistants of the committee" that monitor physicians on a daily basis are all hospital employees.

276. According to a review report of Dr. Durrani performed by Dr. Keith Wilkey, 8 of 16 patients OR reports were not done in a thirty day window, it included a lot of fictitious, fraudulent and false diagnoses, two contraindicated use of Infuse used in minors, one cancer after Infuse and several novel surgeries—VATS, AxiaLIF, DLIF. The results of this peer review speak for itself. Had this study been completed, there is no way to conclude otherwise that Dr. Durrani was incompetent. He should have been summarily suspended before the study was done to protect future patients. The peer review should have reported to the MEC and then Dr. Durrani should have been suspended until a hearing at the MEC

level confirmed or denied the summary suspension. A databank report would have been required to be filed by West Chester.

277. West Chester's bylaws clearly state the requirement that OR reports be done within 30 days from the completion of the surgery. Without exceptions, physicians get written notification of their delinquent records and are given anywhere from seven to ten days to correct the deficiency. If the charts are not dictated within that time limit, the physician is summarily suspended and the case is sent to the MEC for their review. This process may be repeated one or two more times, but usually within a six month period, the delinquent physician has their privileges revoked and a databank report filed. Dr. Durrani was given an exception for over four years.

278. Defendants willingly overlooked illegal operations. Dr. Durrani gave false or exaggerated and fraudulent diagnoses plus fictitious medical treatment. His surgical outcomes were horrible.

279. The hospital has to disclose the OR reports and the report included the time and the date of the dictation, to which the delay from the surgery date can be determined. West Chester had to disclose emails between the hospitals and Dr. Durrani. In one email from the CEO, Defendant Joseph to Dr. Durrani, the CEO acknowledges that they knew of Dr. Durrani's dictation violations. Therefore, they had actual knowledge of Dr. Durrani's violations and cannot claim a statutory presumption of immunity from negligent credentialing.

280. The Joint Commission sets the standard and hospital compliance isn't controlled by the state. Hospitals have to have ongoing physician monitoring in place to satisfy the accreditation requirements. Good hospitals require a medical staff that is willing and able to monitor itself through Practitioner Performance—ongoing professional practice evaluation "OPPE."

281. Since 2009, the Joint Commission has required hospitals, through its medical staff, to conduct an ongoing professional practice evaluation of every privileged practitioner at the hospital, without exception. There are three essentials to OPPE: it must measure certain things (for surgeons, surgical complications and treatment patterns), the measures must be collected and assessed (periodic chart review, observation, discussion with other doctors and nurses), and finally the medical staff must act on its findings (focused professional performance evaluation instituted.) It is a confidential process.

282. Due to the confidentiality, Dr. Durrani's OPPE from the hospital is not available but because West Chester is joint commission accredited and they supposedly meet all their requirements, it is safe to conclude the OPPE process was done two or three times on Dr. Durrani. Once he started at West Chester and then before his re-credentialing every two years. He either resigned, did not reapply, or was revoked around his four year re-credentialing.

283. There is another instance where West Chester administration should have known about the other Dr. Durrani issue in that if the OPPE found problems, the MEC should have required a FPPE, which is an in-depth review with the possible requirement for corrective action, summary suspensions, and recommendation of limitation or termination of privileges. If a FPPE was ongoing and Dr. Durrani resigned during this process, a Databank report should have been filed, which didn't happen.

284. Anytime an event occurs that is significant, called a "trigger" OPPE or an FPPE can be conducted, and given Dr. Durrani's poor performance that should have occurred given a medical staff that was diligent in their duties. The administration had multiple warnings from the medical staff about Dr. Durrani. They knew he was bad and ignored that fact.

**BMP-2**

285. Among Dr. Durrani's and the Hospitals' professional failings was the use of a synthetic bone-morphogenetic protein called BMP-2, which was marketed under the trade

name "Infuse." Dr. Durrani used BMP-2/Infuse in ways that were either not approved by the federal Food and Drug Administration (FDA) or that were specifically contraindicated as noted on the FDA-approved product labeling. The Defendants had full knowledge of this in fact.

286. BMP-2/Infuse was, at the time of the surgeries in question, and currently still is manufactured by a company called Medtronic, Inc. (Medtronic).

287. Dr. Durrani predominantly used BMP-2/Infuse on patients at WCH, which is owned by UC Health.

288. It is Plaintiffs' position that this non-FDA-approved use of BMP-2/Infuse was not only negligent, and fraudulent, but criminal based upon the manner in which it was allowed to be used by Dr. Durrani at West Chester, all with the knowledge and full support of the Defendants.

## I. THE PLAYERS REGARDING BMP-2

289. Dr. Durrani is a citizen of the Republic of Pakistan and was a permanent resident of the United States who, from approximately 2005 to 2013, worked as a spine surgeon in and around Cincinnati, Ohio, until he fled the United States to escape civil liability and criminal prosecution.

290. Medtronic is an Irish corporation, with its principal executive office located in Dublin, Ireland, and its operational headquarters located in Minneapolis, Minnesota. Medtronic is the world's third largest medical device company and manufactures and markets BMP-2/Infuse. Medtronic sales representatives were also present during the experimental surgeries performed on Plaintiffs, who are clients of the Deters Law Firm.

291. CAST was a corporation organized under the laws of Ohio and had business and medical offices in Florence, Kentucky and Evendale, Ohio. CAST was owned, in whole or in part, by Dr. Durrani.

292. Bahler Medical, Inc. is a manufacturer of medical implants and is a corporation located in the state of Ohio.

293. David Rattigan is an Ohio resident and was and is a sales representative for Medtronic. Further, he is affiliated with Bahler Medical, Inc., was involved in many of the transactions involving BMP-2, and was present for the experimental surgeries in which BMP-2 was used.

294. West Chester Hospital, LLC is a corporation organized under the laws of Ohio. It provides medical facilities and billing support to physicians, including Dr. Durrani, in the state of Ohio. WCH is owned by UC Health.

295. UC Health is a private, non-profit corporation organized under the laws of Ohio. It provides medical facilities, management, administrative, ancillary, and billing support to physicians, and it owns WCH.

296. CCHMC is a medical facility in Ohio where Dr. Durrani was an employee until approximately 2008.

## II. WHAT IS BMP-2/INFUSE?

297. The full name of BMP-2 is "Recombinant Human Morphogenetic Protein-2" (also called rhBMP-2). The following definitions apply:

a. Recombinant – Artificially created in a lab;

b. Morphogenetic – Evolutionary development of an organism;

c. Protein – Essential for growth and repair of tissue.

298. Recombinant human protein (rhBMP-2) is currently available for orthopedic usage in the United States.

299. Medtronic manufactured, marketed, sold, and distributed BMP-2 under the trade name "Infuse."

300. BMP-2 has been shown to stimulate the production of bone.

301. Implantation of BMP-2 in a collagen sponge induces new bone formation and can be used for the treatment of bony defects, delayed union, and non-union.

**BMP-2 AS A BIOLOGIC**



302. BMP-2 is not a device, but instead it is a biologic. *See* July 2009 American Medical Association Article and 2011 Stanford School of Medicine Article.

303. According to the FDA, "[a] 'biological product' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings (Public Health Service Act Sec. 351(i)1." Available at http://www.fda.gov/ICECI/Inspections/IOM/ucm122535.htm.

304. BMP-2 is a Bone-Morphogenetic Protein that is used to promote bone creation and remolding and falls under the definition of a biologic. *See* AMA article ("bone forming properties") and Stanford Article. BMP-2 differs from a medical device in that once implanted, it can only be removed days after surgery. If a patient had a complication due to BMP-2 and did not discover this complication until year after surgery, the patient could not have BMP-2 removed to reduce the complication because BMP-2 is so integrated into the patient's bone.

305. A patient has a right to determine what happens to his or her body and the preservation of that right requires that the patient be informed when a bone growth product, that causes irreversible harm, is placed in his or her body.

**WHEN IS IT USED?**

306. Recombinant human BMPs are used in orthopedic applications such as spinal fusions, non-unions, and oral surgery.

307. The bone graft contains two parts. The first is a solution of human bone growth protein or morphogenetic protein-2. This protein is found in the human body in small dosages and is

[1] It should be noted that a biologic can also meet the definitions of drug or device. http://www.fda.gov/ICECI/Inspections/IOM/ucm122535.htm

important for the healing and formation of bones. The protein is genetically engineered to be utilized in the Infuse Bone Graft product, and it is employed for the stimulation of formation and growth in bones.

308. The second part of the bone graft is an absorbable collagen sponge.

309. Both components of the Infuse Bone Graft structure are used to fill the LT-Cage Lumbar Tapered Fusion Device. This chamber is intended to restore the deteriorated disc space to its original height.

310. FDA-approved use for the Infuse Bone Graft product is only for lower back surgery using an anterior lumbar interbody fusion (ALIF), a technique where the operation on the spine is conducted through the abdomen.

311. In addition, the Infuse Bone Graft product must be used in conjunction with Medtronic's LT-Cage. Use of BMP-2 without the LT-Cage is considered an "off-label" use.

**CONTRAINDICATIONS OF USE**

312. The FDA specifically warns against the use of Infuse in the cervical spine, citing reports of "life-threatening complications."

313. Any use of Infuse other than in lumbar spine surgeries with the LT-Cage is considered "off-label" use

314. Infuse should never be used on the skeletally immature patient, i.e., in patients less than 18 years of age or those with no radiographic evidence of epiphyseal closure.

315. Infuse should never be used in the vicinity of a resected or extant tumor.

316. Infuse should never be used in those patients known to have active infection at the surgical site.

**RISKS ASSOCIATED WITH OFF-LABEL USE**

317. When used in an off-label manner, patients may experience problems with pregnancy, including but not limited to: complications in fetal development; allergic reactions to titanium,

bovine type I collagen, or bone morphogenetic protein–2; infection; the creation or intensification of tumors; liver or kidney disease; lupus or human immunodeficiency virus (HIV/AIDS); problems with radiation, chemotherapy, or steroids if a patient is malignant; paralysis; bowel and/or bladder dysfunctions; sexual disorders, including sterilization and incompetence; respiratory failure; excessive bleeding, and; death.

## III. THE REGULATORY PROCESS

318. The Medical Device Amendments (MDA) to the federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., established two separate approval processes for medical devices: Pre–Market Approval (PMA) and Pre–Market Notification.[2]

319. The FDA's PMA process is lengthy and involves extensive investigation by the FDA. The PMA application requires manufacturers to submit extensive animal and human data to establish their devices' safety and effectiveness. 21 C.F.R. § 814.20. Frequently, an experimental program under close FDA scrutiny must be successfully completed before FDA approval can be obtained under this process. FDA regulations also require PMA applicants to submit copies of all proposed labeling for the device. 21 C.F.R. § 814.20(b)(10). The FDA approves a PMA application only after extensive review by the agency and an advisory committee composed of outside experts. 21 C.F.R. § 814.40.[3]

320. In contrast, the FDA's Pre–Market Notification process is more abbreviated and involves less FDA oversight. This process requires applicants to submit descriptions of their devices and other information necessary for the agency to determine whether the devices are substantially equivalent. Pre–Market Notification applicants must also submit their proposed labeling. 21 C.F.R. § 807.87. If the FDA determines that a device is substantially equivalent

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[2] *Fender v. Medtronic*, 887 F.Supp. 1326 fn 1 (E.D. Cal.1995).

[3] *Fender v. Medtronic*, 887 F.Supp. 1326 fn 1 (E.D. Cal.1995).

to a device that was on the market prior to the enactment of the MDA in 1976, the applicant is free to market the device.

321. BMP-2 received PMA (PMA number P000058) for the Infuse/BMP-2 Lumbar Tapered Fusion Device, which PMA provided for limited use with specific requirements for its use on individuals. See Medtronic Package Insert.

**SCOPE OF THE PMA AND PRODUCT LABELING**

322. The PMA for BMP-2 provided that the product may only be used in patients with the following characteristics:

d. Skeletally mature patient, AND

e. At levels L2-S1, AND

f. Confirmed degenerative disc disease (DDD), AND

g. Using only an open anterior or anterior laparoscopic approach, AND[4]

h. Six months of non-operative treatment prior to treatment with the device, AND

i. In combination with the metallic LT-CAGE.[5]

See Medtronic Package Insert, "INDICATIONS."

323. According to Medtronic's package insert for BMP-2/Infuse as well as other industry literature, the following risks are associated with the use of BMP-2/Infuse:

A. Male Sterility

B. Cancer

C. Increased progression of cancer

D. Suffocation of the cervical region

E. Bone fracture

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[4] The anterior interbody fusion approach was developed because the risk of non-union (pseudarthrosis) is significantly higher in posterior approaches. The biggest risk factor for fusion surgery is non-union.

[5] Instrumented fusions involve hardware and are more stable fusions with a shorter recovery time than non-instrumented fusions.

F. Bowel/bladder problems

G. Loss of spinal mobility or function

H. Change in mental status

I. Damage to blood vessels and cardiovascular system compromise

J. Excessive bone mass blocking the ability to treat pain

K. Damage to internal organs and connective tissue

L. Death

M. Respiratory problems

N. Disassembly and migration of components

O. Dural tears

P. Ectopic and exuberant bone formation

Q. Fetal development complications (birth defects)

R. Foreign body (allergic) reaction

S. Gastrointestinal complications

T. Incisional complications

U. Infection

V. Insufflation complications

W. Neurological system compromise

X. Non-union

Y. Delayed union

Z. Mal-union

AA. Change in curvature of spine

BB. Retrograde ejaculation

CC. Scars

DD. Tissue and nerve damage

EE. Itching

FF. Pain

GG. Hematoma

HH. Anaphylactic reaction

II. Elevated erythrocyte sedimentation rate

324. Injury Percentages:

j. Ectopic Bone Growth-63%

k. Inflammatory Neuritis-15%

l. Osteolysis/Subsidence-13%

m. Acute Swelling-7%

n. Retrograde Ejaculation-2%

o. 85% of time, BMP-2 implanted in off-label use

325. Not a single one of these risks in the last two paragraphs were ever explained to a single patient at West Chester by Dr. Durrani.

326. BMP-2 was NOT approved by the FDA for use in the cervical and thoracic spine and BMP-2 was NOT safe or approved for use in children less than 21 years of age. These uses are considered "off-label."

**"OFF-LABEL" USE**

327. A use of a device is considered "off-label" if it is not approved under the Pre-Market Approval process OR cleared for such use pursuant to 21 U.S.C. § 360c(f) (also known as "the 510k premarket notification process").

328. Infuse can be implanted in an off-label manner in three ways:

p. Approach/position: Any approach other than an anterior approach;

q. Product: Failure to use LT-Cage (or any cage); mixing rhBMP-2 with other grafting products like Allograft or Autograft;

r. Discs: Use on multiple levels or on a level outside of L2-S1.

329. Dr. Durrani and the Hospitals in which he performed surgeries repeatedly used BMP-2 in these non-FDA-approved manners.



**THE NON-COMPLIANCE WITH THE REGULATORY PROCESS**

330. The PMA 000058 "Conditions of Approval" specifies the following condition: "Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by the FDA … [a] PMA supplement or alternate submission shall comply with applicable requirements under 21 C.F.R. 814.39[.]"

331. 21 C.F.R. 814.39 requires a PMA supplement pursuant to subsection (a)(1) for new indications of use of the device and pursuant to subsection (a)(6) for changes in components.

332. The PMA 000058 "Conditions of Approval" notes the post-marketing reporting requirement imposed by 21 C.F.R. 814.84, particularly "Identification of changes described in 21 C.F.R. 814.39(a)." Medtronic did not comply with this requirement relating to the intended uses and componentry.

333. The FDA can impose post-approval requirements in the PMA pursuant to 21 C.F.R. 814.82, and this fact results in the device being characterized as "restricted" pursuant to 21 U.S.C. § 360j(e) for purposes of 21 U.S.C. § 352(q). Section 352(q) states that any restricted device that is distributed or offered for sale with false or misleading advertising is "misbranded."

334. "Indications for use" is a necessary part of the PMA application and the "Indications for use" are required to be limited by the application. Any different use is inconsistent with the PMA.

335. A device that fails to meet the requirements of the PMA or 21 C.F.R. 814 is "adulterated" as defined by 21 U.S.C. § 351(f).

336. 21 C.F.R. 801.6 defines a misleading statement related to a DIFFERENT device contained in the label delivered with the device intended to be used will render the device to be used misbranded.

337. Medtronic did not apply for a PMA supplement, as required by the FDA generally and PMA 000058 specifically, for the off-label uses, nor did it provide warnings of the risks known about the off-label uses. All named Defendants in these cases knew about the occurrences of off-label use.

338. The PMA requires an application prior to marketing for new indicated uses by incorporating the federal requirements and explicitly reciting the text of 21 C.F.R. 814.39 and 814.84 and by specifically stating the range of indicated uses on the PMA.

## IV. MEDTRONIC

339. In or about 2001, Medtronic began preparing for the launch of two spinal fusion products, PYRAMID and INFUSE (BMP-2), which it projected would enjoy broad application with spinal surgeons and their patients on a nationwide basis.

340. Medtronic anticipated that both products would initially be limited in application.

341. Motivated by greed and a desire to gain competitive advantage in the marketplace, Medtronic began a course of conduct designed to broaden the application of both products by end-users. The course of conduct involved fraud, false statements, material misrepresentation, and deceit for the purpose of broadening the sales of these products beyond that which the usual acceptance within the scientific community or regulatory approval would otherwise allow.

342. On or after July 2, 2002, Medtronic received notification that its Pre-Market Approval application for its BMP-2/Infuse bone graft products had been approved by the FDA. However, such approval was limited to the application of the device from the L4 through S1 levels. Further, the approval mandated the conduct of post-approval studies to evaluate

the long-term performance of the BMP-2 bone graft and to study the potential side effects and complications such as the promotion of tumors by the bone morphogenetic protein component of BMP-2. Other studies were conducted as well. See "Allegations against Medtronic in the Unsealed Mississippi False Claims Case."

343. Medtronic engaged in a fraudulent course of conduct designed to maximize its revenues from BMP-2, regardless of whether it would eventually be allowed to remain on the market.

344. One of the physicians Medtronic co-opted into its fraudulent scheme was a Thomas A. Zdeblick, M.D. Dr. Zdeblick was an orthopedic surgeon whose invention, the LT-Cage, was the only approved device to act as the delivery vehicle for BMP-2 into the body.

345. Dr. Zdeblick enjoyed a position within the scientific community as a Key Opinion Leader, and he was both a practicing orthopedic surgeon and professor at the University of Wisconsin.

346. In one of Dr. Zdeblick's first attempts to tout his LT-Cage and rhBMP-2, which would become the active ingredient in the ultimate Infuse/BMP-2 product, he encountered some drawbacks to his goal of promoting his and Medtronic's products, which arose from the policy of certain industry journals, including the journal *Spine,* which followed industry standards before printing peer-reviewed material. See article in the journal *Spine,* published in 2000.

347. Not only were the drawbacks related to industry publishing standards, but the National Consumer Health Information and Health Promotion Act of 1976 enacted certain provisions at 42 U.S.C. § 300u, et seq., whereby the Federal Government had entered the field of medical research publication. Such standards promulgated by the Secretary of the predecessor to the U.S. Department of Health and Human Services required that applications for grants and contracts must be subject to "appropriate peer review." See 42 U.S.C. § 300u-1.

348. The drawbacks encountered with the peer-reviewed *Spine* article were as follows:

a. Attribution that the study was "sponsored by Medtronic Sofamor Danek, Inc."

b. The study was conducted under FDA regulations, and was "...designed as a prospective, multicenter, non-blinded, randomized, and controlled pilot study;" and

c. It was accompanied by a cautionary comment, or Point of View, which minimized the exuberance and import of the article.

349. In the article, BMP-2 was touted by Zdeblick and the co-authors as the potential realization of a dream of Dr. Marshall Urist, a revered pioneer in the industry and discoverer of BMP, where it closed with the following: "...it is encouraging to note that Marshall Urist's seminal observation made more than 34 years ago may finally come to clinical fruition."

350. In the Point of View, a Dr. John O'Brien of London questioned whether there could be long-term problems associated with the product. He treated Zdeblick's study with caution and pointed out that simple plaster of Paris has achieved the same or similar results more than 50 years prior. He posited that, "[p]erhaps vascularization...fixation procedures are as important as the biochemical composition of the 'filler.'"

351. Vascularization is achieved through removal of the disc material between two vertebral bodies and then the scraping of the surfaces of the vertebral bodies in a fusion procedure; fixation is the process of securing the motion segment through medical hardware. In other, if the alternative proposed by Dr. O'Brien proved to achieve equivalent or better results, Zdeblick and Medtronic's Infuse/BMP-2 products would be useless and unnecessary.

352. Certain efforts would follow in an attempt to alleviate the drawbacks encountered with the 2000 *Spine* journal article.

353. In 2002, Dr. Zdeblick was installed as the sole editor-in-chief of a medical journal known prior to his installation as the *Journal of Spinal Disorders*. Prior to his installation, the journal enjoyed a fourteen year history under the co-editorship of Dr. Dan Spangler and Dr.

Tom Ducker. Once installed, Dr. Zdeblick successfully supplanted Drs. Dan Spengler and Tom Ducker and became the sole editor-in-chief, a position which would enable him to have greater control and would aid his participation in the fraudulent scheme.

354. During this same time period, Dr. Zdeblick also enjoyed a position on the associate editorial board of the medical journal *Spine*, the leading publication covering all disciplines relating to the spine.

355. In one of Dr. Zdeblick's actions as editor-in-chief, he set about re-purposing the journal in a way that would aid him in the furtherance of the fraudulent scheme through the streamlining of the publication process.

356. In furtherance of the fraudulent scheme, Dr. Zdeblick re-purposed the journal and renamed it the *Journal of Spinal Disorders and Techniques* (JSDT), announcing that the new journal was "entering a new partnership with *Spine*." As part of this partnership, *Spine* would "continue to function as a broad-based scientific journal" tailored to both clinicians and scientists. However, the *Journal of Spinal Disorders and Techniques* would be directed solely to physicians in clinical practice.

357. Dr. Zdeblick's stated goal was "to provide a forum for up-to-date techniques…", and in furtherance of that goal, Dr. Zdeblick announced that his journal would publish Class II or better clinical articles but would "occasionally accept cutting edge articles with less than one year follow-up." To justify this streamlined process, Dr. Zdeblick claimed as his goal the ability of his journal "to keep up with the fast pace of progress in the treatment of spinal patients."

358. Arm-in-arm with Medtronic and others, Dr. Zdeblick would in short order abuse his position of trust as the editor-in-chief of JSDT.

359. In the October 2002 edition, JSDT published an article entitled, "Anterior Lumbar Interbody Fusion using rhBMP-2 with Tapered Interbody Cages." This article was co-authored by, among others, Curtis A. Dickman, M.D., who was a developer of Medtronic's

PYRAMID plate and who has been paid significant sums by Medtronic through royalty agreements, consulting agreements, and education training and speaking agreements.



360. In addition to his interest in the PYRAMID plate, Dr. Dickman had assisted Medtronic in the approval process for Infuse/BMP-2. As part of the pre-approval hearing process, Dr. Dickman and his Barrow Neurological Associates Group of Phoenix, Arizona had submitted a letter to the meeting of the FDA's Orthopedics and Rehabilitation Devices Advisory Panel, which met on January 10, 2002. In that letter, Dr. Dickman represented that "approval of BMP would provide a significant advance for patient outcome and satisfaction following spinal fusion."

361. In the October 2002 issue of JSDT touting the benefits of Infuse/BMP-2, Zdeblick and others failed to disclose their financial ties to Medtronic, though industry standards require such acknowledgement. Not only did Dr. Zdeblick fail to disclose that he profited from each and every surgery which Infuse/BMP-2 was used through rights in the exclusive delivery vehicle, his LT-Cage, but no reference whatsoever to their financial ties to Medtronic was made either by Dr. Zdeblick or Dr. Dickman.

362. For years, the recognized gold standard for spinal bone grafts has been the use of autogenous bone, or bone harvested from the patient's own iliac crest, or hip bone. Medtronic designed to have its Infuse/BMP-2 product supplant autogenous bone as the gold standard in the medical community, and utilized false statements, a fraudulent enterprise and the support of Federal funds to do so.

363. As part and parcel of Medtronic's fraudulent scheme, the October 2002 study was published in Dr. Zdeblick's journal three months after Medtronic received FDA approval for Infuse. As the article shows, it was actually received on March 28, 2002 or after Dr. Zdeblick had accomplished installment as the editor-in-chief, and was accepted by Dr. Zdeblick's journal for publication on July 30, 2002.

364. At the same time Dr. Zdeblick's journal was publishing the initial article on Infuse, Dr. Zdeblick was already finalizing and preparing for subsequent publication a follow-up article to tout Infuse potentially as the new gold standard. A second article, co-authored by Dr. Zdeblick and two other co-authors of the original article, was entitled "Is Infuse Bone Graft Superior to Autograft Bone? An Integrated Analysis of Clinical Trials using the LT-Cage Lumbar Tapered Fusion Device."



365. This second article was published in Vol. 2 of 2003 and once again, there was no mention of Dr. Zdeblick's financial ties to Medtronic.

366. This second article would serve as the second covert advertisement for the Infuse product, and the article states that "the purpose of our analysis was to investigate the potential statistical superiority of Infuse bone graft to autograft..."

367. This second article went on to announce the July 2002 FDA approval of rhBMP-2.

368. This article included as an "acknowledgment" an expression of gratitude to the physicians "who provided patients for this study and to the clinic research group at Medtronic Sofamor Danek for their help in data collection and statistical analyses." However, the article still failed to advise the medical community that some or all of the authors reaching these conclusions touted as monumental had direct financial interests tied to those conclusions.

369. Rather, the failure to report these clear conflicts of interest on the part of those holding positions of trust both within the medical community and over patients was part of Medtronic's fraudulent enterprise. However, unchecked by appropriate peer review, Medtronic was able to systematically accomplish their goals.

370. In its 2003 Annual Report, and without recognizing that Zdeblick was being paid by Medtronic, Medtronic cited to Zdeblick's 2003 as reporting that Infuse "...may become the new gold standard in spinal fusion surgery."

371. By its 2006 Annual Report, if not earlier, Medtronic had removed all doubt, declaring that after its introduction in 2002, "Infuse Bone Graft quickly became the gold standard for certain types of lumbar fusion."

372. Medtronic's fraudulent scheme was successful and resulted in a revenue stream ranging from 700 to 900 million dollars per year.

373. It has been reported that around the same time these stories about Infuse were published, editors at the Spine Journal began receiving complaints from doctors around the country who were pointing out contradictions between papers published by doctors with financial ties to Medtronic and other data involving Infuse complications.' See *Journal Sentinel* article of John Fauber.

374. Through the use of these sham consulting, royalty and education/training agreements with its physician agents in this fraudulent enterprise, Medtronic has reaped windfalls in the billions of dollars. Medtronic has used this fraudulent enterprise and civil conspiracy to drive its vast profits and enhance its market position beyond that which it would have realized without engaging willfully, knowingly and potentially deliberate, conscious, or reckless indifference in the fraudulent enterprise and fraudulent concealment. See Mississippi case.

375. Defendants had full knowledge of all these facts pertaining to Medtronics.

## V. FDA PUBLIC HEALTH NOTIFICATION

376. On July 1, 2008 the FDA issued a Public Health Notification entitled "Life-Threatening Complications Associated with Recombinant Human Bone Morphogenetic Protein in Cervical Spine Fusion."

377. This notification was sent to health care practitioners all across the United States warning of the complications associated with BMP-2, specifically when used in the cervical spine.

378. In the notification the FDA stated they received at least 38 reports of complications during the prior four years with the use of BMP-2 in cervical spine fusions.

379. The complications were associated with swelling of the neck and throat areas, which resulted in compression of the airway and/or neurological structures in the neck.

380. Some reports describe difficulty swallowing, breathing or speaking and severe dysphagia following cervical spine fusion using BMP-2 products had also been reported.

381. The notification further stated that, "since the safety and effectiveness of rhBMP for treatment of cervical spine conditions has not been demonstrated, and in light of the serious adverse events described above, FDA recommends that practitioners either use approved alternative treatments or consider enrolling as investigators in approved clinical studies.

382. The Notification further emphasized the importance of fully informing patients of these potential risks and said that patients treated with BMP-2 in the cervical spine should know:

s. The signs and symptoms of airway complications, including difficulty breathing or swallowing, or swelling of the neck, tongue, mouth, throat and shoulders or upper chest area

t. That they need to seek medical attention immediately at the first sign of an airway complication

u. That they need to be especially watchful 2-14 days after the procedure when airway complications are more likely to occur

v. rhBMP-2 (contained in Infuse Bone Graft) has received pre-market approval for fusion of the lumbar spine in skeletally mature patients with degenerative disc disease at one level from L2-S1 and for healing of acute, open tibial shaft fractures stabilized with an IM nail and treated within 14 days of the initial injury

383. Additionally, BMP is not approved in any manner for use in patients who are skeletally immature (<18 years of age) or pregnant.

384. Dr. Durrani and the Hospitals ignored ALL of these warnings and used BMP-2 in cervical spine surgeries, children, and those with known compromising factors such as osteoporosis, smoking, and diabetes.



385. Furthermore, the Notification stated that the FDA requires hospitals and other facilities to report deaths and serious injuries associated with the use of medical devices.

386. The Hospitals that allowed Dr. Durrani to use BMP-2 in their facilities failed to report any complications resulting from his use of BMP-2.

## VI. SENATE FINANCE COMMITTEE REPORT

387. Medtronic's actions did not go unnoticed, and in June of 2011 the Senate Finance Committee began an investigation into the fraudulent actions of Medtronic.

388. Medtronic produced more than 5,000 documents pertaining to 13 different studies of BMP-2 for the investigation.

389. On October 25, 2012, Senate Finance Committee Chairman Max Baucus (D-Mont.) and senior member Chuck Grassley (R-Iowa) released the results of their 16-month investigation into Medtronic, which revealed questionable ties between the medical technology company and the physician consultants tasked with testing and reviewing Medtronic products.

390. The investigation revealed that Medtronic employees collaborated with physician authors to edit and write segments of published studies on BMP-2/Infuse without publicly disclosing this collaboration.

391. These fraudulently-produced studies may have inaccurately represented BMP-2's risks and may have placed added weight on the side effects of alternative treatments.

392. The Senate investigation further found that Medtronic also maintained significant, previously undisclosed financial ties with physicians who authored studies about BMP-2, making $210 million in payments to physicians over a 15-year period.

393. Senator Baucus stated, "Medtronic's actions violate the trust patients have in their medical care. Medical journal articles should convey an accurate picture of the risks and benefits of drugs and medical devices, but patients are at serious risk when companies distort the facts the way Medtronic has. Patients everywhere will be better served by a more open, honest system without this kind of collusion."



394. Senator Grassley stated, "The findings also should prompt medical journals to take a very proactive approach to accounting for the content of the articles along with the authorship of the articles and the studies they feature. These publications are prestigious and influential, and their standing rests on rigorous science and objectivity. It's in the interest of these journals to take action, and the public will benefit from more transparency and accountability on their part."

395. Major findings of the investigation include:

a. Medtronic was involved in drafting, editing and shaping the content of medical journal articles authored by its physician consultants who received significant amounts of money through royalties and consulting fees from Medtronic. The company's role in authoring or substantially editing these articles was not disclosed in the published articles. Medical journals should ensure that any industry role in drafting articles or contributions to authors is fully disclosed.

b. Medtronic paid a total of approximately $210 million to physician authors of Medtronic-sponsored studies from November 1996 through December 2010 for consulting, royalty and other arrangements.

c. An e-mail exchange shows that a Medtronic employee recommended against publishing a complete list of adverse events, or side effects, possibly associated with BMP-2/Infuse in a 2005 *Journal of Bone and Joint Surgery* article.

d. Medtronic officials inserted language into studies that promoted BMP-2 as a better technique than an alternative by emphasizing the pain associated with the alternative.

e. Documents indicate that Medtronic prepared one expert's remarks to the FDA advisory panel meeting prior to BMP-2 being approved. At the time, the expert was a private physician but was later hired to be a vice president at Medtronic in 2007.

f. Medtronic documents show the company successfully attempted to adopt weaker safety rules for a clinical trial studying BMP-2 in the cervical spine that would have allowed the company to continue the trial in the event that patients experienced severe swelling in the neck.

## VII. YODA STUDY

396. In response to the various controversies surrounding BMP-2/Infuse, including a June 2011 article in the journal *Spine,* the Yale University Open Data Access (YODA) team reached an agreement for Medtronic to provide full individual participant data from all their trials of rhBMP-2 and allow unrestricted independent re-analysis of this data.

397. The YODA study involved research teams at two universities – the University of York and the Oregon Health and Science University.

398. The review focused exclusively on the use of rhBMP-2 in patients undergoing spinal fusion surgery for treatment of degenerative disc disease, spondylolisthesis, or any other relevant spinal condition.

399. The three main objectives of the study were: 1) to examine the potential benefits of BMP-2, 2) to examine the potential harms of BMP-2, and 3) to assess the reliability of the published evidence base.

400. Medtronic submitted data from 17 studies, including 12 randomized controlled trials (RCTs).

401. In total, the YODA study analyzed the data from 1,409 participants.

402. Though the results showed moderate success with fusions as a result of BMP-2, the study found that BMP-2 results in several different complications including arthritis, implant-related events, retrograde ejaculation, wound complications, and neurological, urogenital, and vascular events.



403. In regard to the alleged tampering with the peer-reviewed studies by Medtronic, the YODA study found that only two out of twenty peer-reviewed journal publications reported a comprehensive list of all adverse events that occurred during the studies.

404. Furthermore, the way in which adverse event data was presented in the literature was inconsistent, and the rationale for presenting some adverse events but not others was rarely clear.

405. The study concluded that for the period up to 24 months after surgery, treatment with BMP-2 increases the probability of successful fusion (according to Medtronic definitions and reports, which the study noted "were subjective so it is not possible to confirm whether reported successful fusions truly were successful" see YODA Study, p. 35) but this does not translate to clinically meaningful benefits in pain reduction, function, or quality of life. The small benefits in these outcomes observed from six months onward come at the expense of more pain in the immediate post-operative period and a possible increased risk of cancer.

406. Even more relevant to the case against Dr. Durrani and the Hospitals is the YODA study's conclusion that, "[i]t is very important that these findings are expressed clearly and discussed with patients so that they can make informed choices about the type of surgery they would prefer." *Id.*

407. The University of Oregon Study determined that Infuse/BMP-2 is not better than Autograft, while the University of York study determined that Infuse/BMP-2 offers only a slight and not statistically significant advantage over Autograft.

408. The YODA study concluded that Medtronic "misrepresented the effectiveness and harms through selective reporting, duplicate publication, and underreporting."

409. Adverse event categories such as heterotopic bone formation, osteolysis, and radiculitis were not included in participant databases or internal reports; therefore, the safety profile was not fully assessed.

410. The YODA study further concluded that Medtronic was involved in drafting, editing, and shaping the content of medical journal articles on Infuse/BMP-2 authored by its physician consultants who received significant amounts of money through royalties and consulting fees from Medtronic. The company's significant role in authoring or substantively editing these articles was not disclosed in the published articles.

411. Medtronic paid a total of approximately $210 million to the physician authors of Medtronic-sponsored studies on Infuse from November 1996 through 2010 for consulting, royalty and other arrangements.

412. An email exchange showed that a Medtronic employee recommended against publishing a complete list of adverse events or side effects possibly associated with Infuse in a 2005 *Journal of Bone and Joint Surgery* article.

413. Medtronic officials inserted language into studies that promoted Infuse as a better technique than an alternative procedure by overemphasizing the pain associated with the alternative procedure.

414. Medtronic's actions violated the trust patients have in their medical care. Medical journal articles should convey an accurate picture of the risks and benefits of drugs and medical devices, but patients are at serious risk when companies distort the facts the way Medtronic has. See United States Senate Committee on Finance, October 2012.

415. Infuse was intended for a single level anterior lumbar interbody fusion performed with all three components in a specific spinal region. The three components are a tapered metallic spinal fusion cage (NOT PLASTIC), a recombinant human (BMP) bone Morphogenetic

Protein, and a carrier/scaffold for the BMP and resulting bone. The Infuse product is inserted into the LT-CAGE Lumbar tapered Fusion Device component to form the complete Infuse Bone Graft/LT–Cage Lumbar Tapered Fusion Device. These components must be used as a system. The Infuse Bone Graft component must not be uses without the LT-Cage Lumbar Tapered Fusion Device component.

416. BMP-2 is not supposed to be used in minors.

417. BMP-2 is not supposed to be used with smokers and diabetics because of vascular slowing.

418. BMP-2 should not be used with women in child bearing years.

419. BMP-2 is contraindicated for patients with a known hypersensitivity to rhBMP-2 and should not be used in the vicinity of a resected or extant tumor, in patients with active malignancy, or in patients undergoing treatment for a malignancy.

## VIII. DR. DURRANI AND BMP-2

420. Despite all of these warning signs, Dr. Durrani, with the full knowledge of the Defendants, continued to use BMP-2 in ways not approved by the FDA, or in an "off-label" manner.

421. As early as 2007, Dr. Durrani and UC Health knew there were issues with BMP-2 because insurance companies such as Anthem were refusing to pay for BMP-2.

422. Medtronic provided in writing to Dr. Durrani and CAST the approved uses for Infuse/BMP-2.

423. However, Dr. Durrani and the Defendants continued to use BMP-2 in off-label ways, including but not limited to:

a. Using BMP-2/Infuse in children, despite Medtronic specifically requiring it be used only in "skeletally mature patients;"

b. Using it outside the L2-S1 level of the spine;

c. Ignoring the requirement that BMP-2/Infuse only be used for Grade 1 spondylolisthesis or Grade 1 retrolisthesis;

d. Not requiring at least six months of non-operative treatment prior to the use of BMP-2/Infuse;

e. Using BMP-2/Infuse without the required cage;

f. Not using the "carrier scaffold" in conjunction with BMP-2/Infuse as required;

g. Using BMP-2/Infuse without proper training despite Medtronic's warning, "Caution: Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training or experience."



424. Dr. Durrani was a paid consultant for Medtronic.

425. According to Dr. Durrani's own deposition testimony in several cases, Medtronic required one of their representatives to be present in the operating room when its product BMP-2/Infuse is used.

426. Because Medtronic representatives were present in these surgeries, Medtronic knew when Dr. Durrani used BMP-2/Infuse outside the approved uses according to Medtronic's own guidelines.

427. Dr. Durrani was encouraged by Medtronic to obtain peer review and published studies from Medtronic sales representatives to support his use of BMP-2/Infuse.

428. Dr. Durrani was encouraged by Medtronic to be an advocate for his patients and describe how BMP-2/Infuse technology can benefit them.

429. When asked how he got his Medtronic grant, Dr. Durrani responded, "You apply to the Medtronic's corporate and say this is what we want to do, like everybody else in the country applies, and then they come and evaluate the thing and say, "Okay, we think it's worthy. We'll give you the grant."

430. In regard to his role as a Medtronic consultant, Dr. Durrani stated, "If there are certain products that they help us in developing, then they will come to us for a certain consultant role for a certain product development."

431. Dr. Durrani also stated, "I was involved in the development of the minimally invasive spine instrumentation."

432. Dr. Durrani gave conflicting reports on his financial relationship with Medtronic.

433. In a deposition, when asked when his relationship with Medtronic began, Dr. Durrani responded "2000-it's 2003, '04. Something in that category. I'm not sure. It's on the Medtronic website. You can go look at it."

434. Medtronic's website has no information regarding their relationship with Dr. Durrani.

435. In another deposition, Dr. Durrani stated he began his relationship with Medtronic in "2005 or '06."

436. Dr. Durrani also gave conflicting reports on how much compensation he received from Medtronic for his consultation services.

437. In one deposition, Dr. Durrani stated in response to an inquiry as to how much payment he received, "It's a standard compensation. Again, it's on the website, how much they've paid us."

438. Again, this information is not available on the Medtronic website.

439. In another deposition, when asked if he received income from Medtronic, Dr. Durrani replied, "No, I don't."

440. When questioned further if he received a fee as a consultant, he stated, "If you do a work, there is a contractual obligation that they have to pay you. As I told you in my last deposition, they did declare it on their website, so you can actually go on the website and see how much they paid."

441. In another deposition, Dr. Durrani stated that he received, "less than $10,000 in ten years" from Medtronic.

442. An email dated July 30, 2008 from Medtronic Senior Product Manager Katie Stamps to Dr. Durrani states that she "is in the process of working on the renewal of your [Dr. Durrani's] consulting agreement." As stated, this information is not available on Medtronic's website, nor is any information relating to Dr. Durrani's role as a consultant for Medtronic.

443. A CCHMC packet relating to its Orthopedics department indicated that Dr. Durrani received $60,000 in grants, contracts, or industry agreements from Medtronic Sofamor Danek in FY 2008.

444. Financial information discovered concerning Dr. Durrani's relationship with Medtronic was found in Dr. Durrani's biography on the website for the Orthopaedic & Spine Institute, which Dr. Durrani currently operates in Pakistan. The biography states that "Dr. Atiq Dr. Durrani has also received the Clinical Spine Fellowship Grant by the Department of Orthopaedic Surgery which was funded by Medtronic Sofamor Danek with a budget of $59,170 per year." See http://www.osi.com.pk/doctor/dr-atiq-Dr. Durrani-md/.

445. When a request was made to Medtronic regarding its affiliation with Dr. Durrani, the Medtronic Supplier Relations Team stated that Dr. Durrani's "name [is] not listed in our system."

446. Medtronic further responded to the Deters Law Firm's request that the firm would need a "Vendor I.D. Number," which neither Medtronic nor any other party has provided.

447. David Rattigan, Dr. Durrani's main Medtronic representative from Bahler Medical, is actively fighting a subpoena to a give a deposition in these cases.

448. David Rattigan and Medtronic have the same lawyer. Despite the Deters Law Firm's willingness to cooperate in scheduling the date for a deposition, they have refused until recently. Mr. Rattigan's deposition is currently scheduled for the month of June, 2015.

449. In summary, clients of the Deters Law Firm, with the full knowledge and intentional consent of all Defendants, became unsuspecting experiments for real world testing of Medtronic hardware and BMP-2, by and through Dr. Durrani and CAST, who had secret

financial connections to Medtronic, improper motives, and submitted false claims. The government paid for many of these improper and unregulated experiments as a result of the false claims made by Dr. Durrani, with the knowledge of Medtronic, under the veil of "medically necessary" surgeries.



450. Despite repeated requests, Medtronic has refused to cooperate in providing any requested information and is actively downplaying their connections to Dr. Durrani.

## IX. THE DEFENDANTS AND BMP-2

451. The Defendants allowed and encouraged these practices by Dr. Durrani for the sole purpose of money and greed.

452. David Rattigan was always present in Dr. Durrani's operating rooms as a representative of Medtronic.

453. David Rattigan's sole job was to deliver the BMP-2/Infuse to the Hospitals and make sure that it was inserted correctly into the patient.

454. David Rattigan's presence in the OR further supports the Defendants awareness of Dr. Durrani's fraudulent use of BMP-2/Infuse.

455. Dennis Robb, the Senior Vice President of Operations and Chief Supply Officer for UC Health[6] spends $369 million annually and 73% of his budget on contracting[7].

456. Robb was intimately familiar with BMP-2/Infuse and was in charge of acquiring the product for UC Health, which would then keep an inventory of BMP-2/Infuse and supply and distribute it to the Hospitals out of the warehouse as needed.

457. Robb would place an order with Medtronic, Medtronic would deliver BMP-2/ Infuse to the UC Health Business Center warehouse, and Robb would do a three-way match based on what he ordered, what Medtronic delivered, and the price quoted by Medtronic.

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[6] Robb Deposition Page 8, Brenda Shell Case
[7] Robb Deposition Page 10

458. The BMP-2/Infuse would be distributed to West Chester from the UC Health Business Center warehouse almost on a daily basis (five to six times a week) based on the inventory demand.

459. UC Health clearly was involved in placing BMP-2/Infuse into the stream of commerce by storing, supplying, and distributing BMP-2/Infuse to its hospitals as needed for surgeries.

460. Despite this awareness, the Defendants NEVER obtained its patients' informed consent regarding the experimental and fraudulent use of BMP-2/Infuse.

461. The **WCH Policy and Procedure Manual** states, in part:

**Risk Management: Acknowledgment of Informed Consent. Policy:**

No examination or treatment may commence without the consent of the patient or the patient's legally authorized representative.

The principle of informed consent is based on the individual's right to privacy and self-determination, which includes the right to make informed, reasoned decisions concerning one's physical and mental well-being.

It is the responsibility of the treating physician to obtain informed consent.

A nurse may witness the signature of the patient on the Acknowledgment of Informed Consent form if the patient verbalizes an understanding of the procedure, risks, benefits, and alternatives, as explained by the physician.

Informed Consent for surgical or medical procedure and sedation:

a. It is the responsibility of the attending physician to obtain informed consent prior to the procedure. The patient, or his/her representative, will be advised by his/her physician of:

b. The explanation of the procedure

c. The benefits of the procedure

d. The potential problems that might occur during recuperation

e. The risks and side effects of the procedure which could include but are not limited to severe blood loss, infection, stroke or death.

f. The benefits, risks and side effect of alternative procedures including the consequences of declining this procedure or any alternative procedures.

g. The likelihood of achieving satisfactory results

The patient's consent must be documented for:

a. Surgical procedures and invasive procedures
b. Medical regimens of substantial risk, or that are the subject of human investigations or research must be in writing, and signed and dated by the patient or his/her authorized representative.

462. **WCH/UC Health Policy #ADM.02,** states in part:

a. No examination or treatment may consent without the consent of the patient or the patient's legally authorized representative.

b. The principle of informed consent is based on the individual's right to privacy and self-determination which includes the right to make informed, reasoned decisions concerning one's physical and mental well-being.

c. It is the responsibility of the treating physician to obtain informed consent.

**Informed Consent for Surgical or Medical Procedure and Sedation:**

It is the responsibly of the attending physician to obtain informed consent prior to the procedure. The patient, or his/her representative, will be advised by his/her physician of:

a. The explanation of the procedure

b. The benefits of the procedure

c. The potential problems that might occur during recuperation

d. The risks and side effects of the procedure which could include but are not limited to severe blood loss, infection, stroke or death.

e. The benefits, risks and side effect of alternative procedures including the consequences of declining this procedure or any alternative procedures.

f. The likelihood of achieving satisfactory results

Completion of the "Consent to Hospital and Medical Treatment" form to examine and treat is NOT sufficient as consent to perform a surgical procedure, invasive procedure, or for medical regimens of substantial risk or that are the subject of human investigation or research.

463. WCH requires its own written consent because it knows its responsibility. It cannot require its own written consent and then "wash its hands" of the responsibility.

464. The Defendants had the responsibility to carry out these consent rules.

465. Dr. Durrani oftentimes used BMP-2 and/or Puregen "off-label" when performing surgeries.

466. BMP-2 is manufactured, marketed, sold and distributed by Medtronic under the trade name "Infuse."

467. Dr. Durrani is a consultant for Medtronic.

468. Defendants did not inform Plaintiff of Durrani's financial interest, conflicts of interest or consulting arrangement with Medtronic.

469. Medtronic, provided in writing to Dr. Durrani and CAST the approved uses for BMP-2, the substance also referred to as Infuse, which is a bone morphogenic protein, used as an artificial substitute for bone grafting in spine surgeries.

470. BMP-2 is not approved by the Food and Drug Administration for use in the thoracic spine.

471. BMP-2 is neither safe nor approved for use on children less than twenty one (21) years of age.

472. For use in spinal surgery, BMP-2/Infuse is approved by the FDA for a limited procedure, performed on a limited area of the spine, using specific components. Specifically, the FDA approved Infuse for one procedure of the spine: Anterior Lumbar Interbody Fusion ("ALIF" or "Anterior" approach); and only in one area of the spine: L4 to S1; and only when used in conjunction with FDA-Approved Components: LT-CAGE Lumbar Tapered Fusion Device Component ("LT-CAGE")

473. Use of Infuse in cervical or thoracic surgery, or use through the back (posterior), or side (lateral), or on areas of the spine outside of the L4-S1 region (e.g., the cervical spine), or using components other than or in addition to the LT-CAGE is not approved by the FDA, and thus such procedures and/or use of non-FDA approved componentry is termed "off-label."

474. When used off-label, Infuse frequently causes excessive or uncontrolled (also referred to as "ectopic" or "exuberant") bone growth on or around the spinal cord. When nerves are compressed by such excessive bone growth, a patient can experience, among other adverse events, intractable pain, paralysis, spasms, and cramps in limbs.



475. The product packaging for BMP-2/Infuse indicates it causes an increased risk of cancer four (4) times greater than other bone graft alternatives.

476. Dr. Durrani, CAST staff and employees, and West Chester/UC Health personnel did not disclose to Plaintiff their intent to use BMP-2/Infuse, and further, did not disclose their intent to use BMP-2/Infuse in a way not approved by the FDA.

477. Dr. Durrani used BMP-2 in Plaintiff in a manner not approved by Medtronic or the FDA.

478. Plaintiff was not informed by Defendants that Dr. Durrani used Infuse/BMP-2 in her surgeries.

479. Plaintiff would not have allowed BMP-2 to be used by Dr. Durrani in her surgeries in a manner that was not approved by the FDA or Medtronic, Infuse/BMP-2's manufacturer.

480. Plaintiff would not have consented to the use of BMP-2 in her body if informed of the risks by Dr. Durrani, CAST staff and employees, or any West Chester/UC Health personnel.

481. The written informed consent of Dr. Durrani and CAST signed by Plaintiff lacked the disclosure of Infuse/BMP-2's use in her procedures.

482. Plaintiff never received a verbal disclosure of Infuse/BMP-2 from Dr. Durrani, CAST staff and employees, or any West Chester/UC Health personnel.

483. Medtronic specifically required Infuse/BMP-2 only be used in "skeletally mature patients" with degenerative disc disease.

484. Medtronic required at least six (6) months of non-operative treatment prior to use of Infuse/BMP-2.

485. Dr. Durrani regularly used Infuse/BMP-2 without this six (6) month non-operative treatment.

486. Medtronic required BMP-2 always be used in conjunction with a metal LT cage.

487. Dr. Durrani regularly used BMP-2 without a proper LT cage in his surgeries.

**INFUSE/BMP-2**

488. Dr. Durrani oftentimes used BMP-2 "off-label" when performing surgeries.

489. BMP-2 is manufactured, marketed, sold and distributed by Defendant Medtronic under the trade name "Infuse."

490. Dr. Durrani is a consultant for Medtronic.

491. Defendants did not inform Plaintiff of Durrani's financial interest, conflicts of interest or consulting arrangement with Medtronic.

492. Medtronic, provided in writing to Dr. Durrani and CAST the approved uses for BMP-2, the substance also referenced to as Infuse, which is a bone morphogenic protein, used as an artificial substitute for bone grafting in spine surgeries.

493. BMP-2 is not approved by the Food and Drug Administration for use in the cervical and thoracic spine.

494. BMP-2 is neither safe nor approved for use on children less than twenty one (21) years of age.

495. For use in spinal surgery, BMP-2/Infuse is approved by the FDA for a limited procedure, performed on a limited area of the spine, using specific components. Specifically, the FDA approved Infuse for one procedure of the spine: Anterior

Lumbar Interbody Fusion ("ALIF" or "Anterior" approach); and only in one area of the spine: L4 to Sl; and only when used in conjunction with FDA-Approved Components: LT-CAGE Lumbar Tapered Fusion Device Component ("LT- CAGE")



496. Use of Infuse in cervical or thoracic surgery, or use through the back (posterior), or side (lateral), or on areas of the spine outside of the L4-Sl region (e.g., the cervical spine), or using components other than or in addition to the LT-CAGE is not approved by the FDA, and thus such procedures and/or use of non-FDA approved componentry is termed "off-label."

497. When used off-label, Infuse frequently causes excessive or uncontrolled (also referred to as "ectopic" or "exuberant") bone growth on or around the spinal cord. When nerves are compressed by such excessive bone growth, a patient can experience, among other adverse events, intractable pain, paralysis, spasms, and cramps in limbs.

498. The product packaging for BMP-2/Infuse indicates it causes an increased risk of cancer four (4) times greater than other bone graft alternatives.

499. Dr. Durrani, CAST staff and employees, and Christ Hospital personnel did not disclose to Plaintiff their intent to use BMP-2/Infuse, and further, did not disclose their intent to use BMP-2/Infuse in a way not approved by the FDA.

500. Dr. Durrani used BMP-2 in Plaintiff in a manner not approved by Medtronic or the FDA.

501. Plaintiff was not informed by Defendants that Dr. Durrani used Infuse/BMP-2 in her surgery.

502. Plaintiff would not have allowed BMP-2 to be used by Dr. Durrani in her surgery in a manner that was not approved by the FDA or Medtronic, Infuse/BMP-2's manufacturer.

503. Plaintiff would not have consented to the use of BMP-2 in her body if informed of the risks by Dr. Durrani, CAST staff and employees, or any Christ Hospital personnel.

504. The written informed consent of Dr. Durrani and CAST signed by Plaintiff lacked the disclosure of Infuse/BMP-2 's use in her procedures.

505. Plaintiff never received a verbal disclosure of Infuse/BMP-2 from Dr. Durrani, CAST staff and employees, or any Christ Hospital persom1el.

506. Medtronic specifically required Infuse/BMP-2 only be used in "skeletally mature patients" with degenerative disc disease.

507. Medtronic required at least six (6) months of non-operative treatment prior to use of Infuse/BMP-2.

508. Dr. Durrani regularly used Infuse/BMP-2 without this six (6) month non- operative treatment.

509. Medtronic required BMP-2 always be used in conjunction with a metal LT cage.

510. Dr. Durrani regularly used BMP-2 without a proper LT cage in his surgeries.

**PUREGEN**

511. Dr. Dunani oftentimes used Puregen when performing surgeries.

512. Puregen is a product produced by Alphatec Spine.

513. Dr. Durrani was and is a paid consultant for Alphatec Spine.

514. Dr. Durrani has an ownership stake in the Alphatec Spine.

515. Puregen has never been approved by the FDA for any human use.

516. Puregen is now removed from the market for any use.

517. Dr. Durrani used the product Puregen as bone graft substitute similar to Infuse/BMP-2 during spinal surgeries.

518. Dr. Durrani, CAST staff and employees, and Christ Hospital personnel did not disclose their intent to use Puregen, nor did they inform Plaintiff that it was a product that was not approved by the FDA for human use.

519. Dr. Durrani used Puregen in Plaintiff in manners not approved by the FDA.

520. Plaintiff was not informed by Dr. Durrani, CAST staff and employees, or any Christ Hospital personnel that Dr. Durrani used Puregen in her surgery.

521. Plaintiff would not have allowed Puregen to be used by Dr. Durrani in her surgery in a manner that was not approved by the FDA.

522. Plaintiff would not have consented to the use of Puregen in her body if informed of the risks by Dr. Durrani, CAST staff and employees, or any Christ Hospital personnel.

523. The written informed consent of Dr. Durrani and CAST signed by Plaintiff lacked the disclosure of Puregen's use in her procedures.

524. Plaintiff never received a verbal disclosure of Puregen from Dr. Durrani, CAST staff and employees, or any Christ Hospital personnel.

**DR. DURRANI COUNTS:**

**COUNT I: NEGLIGENCE**

525. Defendant Dr. Durrani owed his patient, Plaintiff, the duty to exercise the degree of skill, care, and diligence an ordinarily prudent health care provider would have

exercised under like or similar circumstances.

526. Defendant Dr. Durrani breached his duty by failing to exercise the requisite degree of skill, care and diligence that an ordinarily prudent health care provider would have exercised under same or similar circumstances through, among other things, negligent diagnosis, medical mismanagement and mistreatment of Plaintiff, including but not limited to improper selection for surgery, improper performance of the surgery, and improper follow-up care addressing a patient's concerns.

527. As a direct and proximate result of the aforementioned negligence and deviation from the standard of care on the part of the Defendant Dr. Durrani, Plaintiff sustained all damages requested in the Prayer for Relief.

**COUNT II: BATTERY**

528. Dr. Durrani committed battery against Plaintiff by performing a surgery that was unnecessary, contraindicated for Plaintiffs medical condition, and for which he did not properly obtain informed consent, inter alia, by using BMP-2, PureGen and/or Baxano in ways and for surgeries not approved by the FDA and medical community, and by the failure to provide this information to Plaintiff.

529. Plaintiff would not have agreed to the surgery if they knew the surgery was unnecessary, not approved by the FDA, and not indicated.

530. As a direct and proximate result of the aforementioned battery by Dr. Durrani, Plaintiff sustained all damages requested in the Prayer for Relief.

## COUNT III: LACK OF INFORMED CONSENT

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531. The informed consent forms from Dr. Durrani and CAST which they required Plaintiff to sign failed to fully cover all the information necessary and required for the procedures and surgical procedures performed by Dr. Durrani. Dr. Durrani and CAST each required an informed consent release.

532. In addition, no one verbally informed Plaintiff of the information and risks required for informed consent at the time of or before Plaintiffs surgery.

533. Dr. Durrani failed to inform Plaintiff of material risks and dangers inherent or potentially involved with her surgery and procedures.

534. Had Plaintiff been appropriately informed of the need or lack of need for surgery and other procedures and the risks of the procedures, Plaintiff would not have undergone the surgery or procedures.

535. As a direct and proximate result of the lack of informed consent, Plaintiff sustained all damages requested in the Prayer for Relief.

## COUNT IV: INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

536. Dr. Durrani's conduct as described above was intentional and reckless.

537. It is outrageous and offends against the generally accepted standards of morality.

538. It was the proximate and actual cause of Plaintiffs psychological injuries, emotional injuries, mental anguish, suffering, and distress.

539. Plaintiff suffered severe distress and anguish so serious and of a nature that no reasonable man or woman would be expected to endure.

## COUNT V: FRAUD

540. Dr. Durrani made material, false representations to Plaintiff and their insurance company related to Plaintiffs treatment including: stating the surgery was

necessary, that Dr. Durrani "could fix" Plaintiff, that more conservative treatment was necessary and futile, that the surgery would be simple or was "no big deal", that Plaintiff would be walking normally within days after each surgery, that the procedures were medically necessary and accurately reported on the billing to the insurance company, that the surgery was successful, and that Plaintiff was medically stable and ready to be discharged.

541. Dr. Durrani also concealed the potential use of Infuse/BMP-2 and/or Puregen in Plaintiff's surgery, as well as other information, when he had a duty to disclose to Plaintiff his planned use of the same.

542. These misrepresentations and/or concealments were material to Plaintiff because they directly induced Plaintiff to undergo her surgery.

543. Dr. Durrani knew or should have known such representations were false, and/or made the misrepresentations with utter disregard and recklessness.

544. Dr. Durrani made the misrepresentations before, during and after the surgery with the intent of misleading Plaintiff and their insurance company into relying upon them. Specifically, the misrepresentations were made to induce payment by the insurance company, without which Dr. Durrani would not have performed the surgery, and to induce Plaintiff to undergo the surgery without regard to medical necessity and only for the purpose of receiving payment.

545. The misrepresentations and/or concealments were made during Plaintiff's office visits at Dr. Durrani's CAST offices.

546. Plaintiff was justified in their reliance on the misrepresentations because a patient has a right to trust their doctor and that the facility is overseeing the doctor to ensure the patients of that doctor can trust the facility.

547. As a direct and proximate result of the aforementioned fraud, Plaintiff did undergo surgery which was paid for in whole or in part by their insurance company, and suffered all damages as requested in the Prayer for Relief.

**COUNT VI: SPOLIATION OF EVIDENCE**

548. Dr. Durrani willfully altered, destroyed, delayed, hid, modified and/or spoiled ("spoiled") Plaintiffs records, emails, billing records, paperwork and related evidence.

549. Dr. Durrani spoiled evidence with knowledge that there was pending or probable litigation involving Plaintiff.

550. Dr. Durrani's conduct was designed to disrupt Plaintiffs potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiff.

**CAST COUNTS:**

**COUNT 1: VICARIOUS LIABILITY**

551. At all times relevant, Defendant Dr. Durrani was an agent, and/or employee of CAST.

552. Dr. Durrani is in fact, the owner of CAST.

553. Defendant Dr. Durrani was performing within the scope of his employment with CAST during the care and treatment of Plaintiff.

554. Defendant CAST is responsible for harm caused by acts of its employees for conduct that was within the scope of employment under the theory of respondeat superior.

555. Defendant CAST is vicariously liable for the acts of Defendant Dr. Durrani alleged in this Complaint including all of the counts asserted against Dr. Durrani directly.

556. As a direct and proximate result of Defendant CAST's acts and omissions, Plaintiff sustained all damages requested in the Prayer for Relief.

**COUNT II: NEGLIGENT HIRING, RETENTION, AND SUPERVISION**

557. CAST provided Dr. Durrani, inter alia, financial support, control, medical facilities, billing and insurance payment support, staff support, medicines, and tangible items for use on patients.

558. CAST and Dr. Durrani participated in experiments using BMP-2 and/or Puregen bone graft on patients, including Plaintiff, without obtaining proper informed consent thereby causing harm to Plaintiff.

559. CAST breached its duty to Plaintiff, inter alia, by not supervising or controlling the actions of Dr. Durrani and the doctors, nurses, staff, and those with privileges, during the medical treatment of Plaintiff at CAST.

560. The Safe Medical Device Act required entities such as CAST to report serious injuries, serious illnesses, and deaths related to failed medical devices to the FDA and the manufacturer; this was never done.

561. Such disregard for and violations of federal law represents strong evidence that CAST negligently hired, retained, and supervised Dr. Durrani.

562. As a direct and proximate result of the acts and omissions herein described, including but not limited to failure to properly supervise medical treatment by Dr. Durrani, Plaintiff sustained all damages requested in the Prayer for Relief.

**COUNT III: SPOLIATION OF EVIDENCE**

563. CAST, through its agents and employees, willfully altered, destroyed, delayed, hid, modified and/or spoiled ("spoiled") Plaintiffs records, emails, billing records, paperwork and related evidence.

564. CAST, through its agents and employees, spoiled evidence with lmowledge that there was pending or probable litigation involving Plaintiff.

565. CAST's conduct was designed to disrupt Plaintiffs potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiff.

**COUNT IV: OHIO CONSUMER SALES PROTECTION ACT**

566. Although the Ohio Consumer Sales Protection statutes O.R.C 1345.01 et seq. exempts physicians, a transaction between a hospital and a patient/consumer is not clearly exempted.

567. CAST's services rendered to Plaintiff constitute a "consumer transaction" as defined in ORC Section 1345.01(A).

568. CAST omitted suppressed and concealed from Plaintiff facts with the intent that Plaintiff rely on these omissions, suppressions and concealments as set forth herein.

569. CAST's misrepresentations, and its omissions, suppressions and concealments offact, as described above, constituted unfair, deceptive and

unconscionable acts and practices in violation ofO.R.C 1345.02 and 1345.03 and to Substantive Rules and case law.

570. CAST was fully aware of its actions.

571. CAST was fully aware that Plaintiff was induced by and relied upon CAST's representations at the time CAST was engaged by Plaintiff.

572. Had Plaintiff been aware that CAST's representations as set forth above were untrue, Plaintiff would not have used the services of Defendants.

573. CAST, through its agency and employees knowingly committed the unfair, deceptive and/or unconscionable acts and practices described above.

574. CAST's actions were not the result of any bona fide errors.

575. As a result of CAST's unfair, deceptive and nnconscionable acts and practices, Plaintiff has suffered and continues to suffer damages, which include, but are not limited to the following:

a. Loss of money paid

b. Severe aggravation and inconveniences

c. Under O.R.C. 1345.01 Plaintiff is entitled to:

i. An order requiring that CAST restore to Plaintiff all money received from Plaintiff plus three times actual damages and/or actual/statutory damages for each violation;

ii. All incidental and consequential damages incurred by Plaintiff;

iii. All reasonable attorneys' fees, witness fees, court costs and other fees incurred;

**CHRIST HOSPITAL COUNTS:**

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**COUNT I: NEGLIGENCE**

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576. Christ Hospital owed their patient, Plaintiff, through its agents and employees a duty to exercise the degree of skill, care, and diligence an ordinarily prudent health care provider would have exercised under like or similar circumstances.

577. Christ Hospital acting through its agents and employees breached their duty by failing to exercise the requisite degree of skill, care and diligence that an ordinarily prudent health care provider would have exercised under same or similar circumstances through, among other things, negligent diagnosis, medical mismanagement and mistreatment of Plaintiff: including but not limited to improper selection for surgery, improper performance of the surgery, improper assistance during Plaintiffs surgery and improper follow up care addressing a patient's concerns.

578. The agents and employees who deviated from the standard of care include nurses, physician assistants, residents and other hospital personnel who participated in Plaintiffs surgery.

579.

579. The management, employees, nurses, technicians, agents and all staff during the scope of their employment and/or agency of Christ Hospital's knowledge and approval, either knew or should have known the surgery was not medically necessary based upon Dr. Durrani's known practices; the pre-op radiology; the pre-op evaluation and assessment; and the violation of their responsibility under the bylaws, rules, regulations and policies of Christ Hospital.

580. As a direct and proximate result of the aforementioned negligence and deviation from the standard of care by the agents and employees of Christ Hospital, Plaintiff sustained all damages requested in the Prayer for Relief.

## COUNT II: NEGLIGENT CREDENTIALING, SUPERVISION, AND RETENTION

581. As described in the Counts asserted directly against Dr. Durrani, the actions of Dr. Durrani with respect to Plaintiff constitute medical negligence, lack of informed consent, battery, and fraud.

582. Christ Hospital negligently credentialed, supervised, and retained Dr. Durrani as a credentialed physician, violating their bylaws and JCAHO rules by:

a. Allowing Dr. Dunani to repeatedly violate the Christ Hospital bylaws with it's full knowledge of the same;

b. Failing to adequately review, look into, and otherwise investigate Dr. Durrani's educational background, work history and peer reviews when he applied for and reapplied for privileges at West Chester Hospital;

c. Ignoring complaints about Dr. Durrani's treatment of patients reported to it by West Chester Hospital staff, doctors, Dr. Durrani' s patients and by others;

d. Ignoring information they knew or should have known pertaining to Dr. Durrani's previous privileged time at other Cincinnati area hospitals, including Children's Hospital, University Hospital, Deaconess Hospital, Good Samaritan Hospital and Christ Hospital.

583. The Safe Medical Device Act required entities such as Christ Hospital to

report serious injuries, serious illnesses, and deaths related to failed medical devices to the FDA and the manufactmer; this was never done.

584. As a direct and proximate result of the negligent credentialing, supervision, and retention of Dr. Durrani, Plaintiff sustained all damages requested in the Prayer for Relief.

**COUNT III: FRAUD**

585. Christ Hospital sent out billing to Plaintiff at her home following her surgery at West Chester Hospital.

586. The exact dates these medical bills were sent out are reflected in those medical bills.

587. These bills constituted affirmative representations by Christ Hospital that the charges related to Plaintiffs smgery were medically appropriate and properly documented.

588. The bills were sent with the knowledge of Christ Hospital that in fact Plaintiffs surgery was not appropriately billed and documented and that the services rendered at Christ Hospital associated with Dr. Durrani were not appropriate.

589. The bills sent by Christ Hospital to Plaintiff falsely represented that Plaintiffs surgery was appropriately indicated, performed and medically necessary in contra-indication of the standard of care.

590. Christ Hospital billed Plaintiff for "OR ALLOGRAFTS" in the amount of $1,821.69 and $12393.00;" upon information and belief, Plaintiff believes that these charges are for the use of Infuse/BMP-2 and/or Puregen.

591. Plaintiff relied on the facility holding Dr. Durrani out as a surgeon and allowing him to perform smgery at its health care facility as assurance the facility was overseeing Dr. Durrani, vouching for his surgical abilities, and further was

appropriately billing Plaintiff for Christ Hospital's services in association with Dr. Durrani's surgery.

592. As a direct and proximate result of this reliance on the billing of Christ Hospital, Plaintiff incurred medical bills that he otherwise would not have incurred.

593. Christ Hospital also either concealed from Plaintiff facts they knew about Dr. Durrani, including that Infuse/BMP-2 or Puregen would be used in Plaintiffs surgery, or misrepresented to Plaintiff the nature of the surgery, and the particular risks that were involved therein.

594. Christ Hospital's concealments and misrepresentations regarding Infuse/BMP-2 or Puregen and the nature and risks of Plaintiffs surgery were material facts.

595. Because of its superior position and professional role as a medical service provider, Christ Hospital had a duty to disclose these material facts to Plaintiff and a duty to refrain from misrepresenting such material facts to Plaintiff.

596. Christ Hospital intentionally concealed and/or misrepresented said material facts with the intent to defraud Plaintiff in order to induce Plaintiff to undergo the surgery, and thereby profited from the surgery and procedures Dr. Durrani performed on Plaintiff at Christ Hospital.

597. Plaintiff was unaware that Infuse/BMP-2 or Puregen would be used in Plaintiffs surgery and therefore, was unaware of the health risks of Infuse/BMP-2 or Puregen's use in Plaintiffs spine.

598. Had Plaintiff known before Plaintiffs surgery that Infuse/BMP-2 or Puregen would be used in Plaintiffs spine and informed of the specific, harmful risks flowing therefrom, Plaintiff would not have undergone the surgery with Dr. Durrani at Christ Hospital.

599. As a direct and proximate result of the fraud upon Plaintiff by Christ Hospital, Plaintiff sustained all damages requested in the prayer for relief.

## COUNT IV: SPOLIATION OF EVIDENCE

600. Christ Hospital through its agents and employees, willfully altered, destroyed, delayed, hid, modified and/or spoiled ("spoiled") Plaintiffs records, emails, billing records, paperwork and related evidence.

601. Christ Hospital through its agents and employees, spoiled evidence with knowledge that there was pending or probable litigation involving Plaintiff.

602. Christ Hospital's conduct was designed to disrupt Plaintiffs potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiff.

## COUNT V: OHIO CONSUMER SALES PROTECTION ACT

603. Although the Ohio Consumer Sales Protection statutes O.R.C 1345.01 et seq. exempts physicians, a transaction between a hospital and a patient/consumer is not clearly exempted.

604. Christ Hospital's services rendered to Plaintiff constitute a "consumer transaction" as defined in ORC Section 1345.01(A).

605. Christ Hospital omitted suppressed and concealed from Plaintiff facts with the intent that Plaintiff rely on these omissions, suppressions and concealments as set forth herein.

606. Christ Hospital's misrepresentations, and its omissions, suppressions and concealments of fact, as described above, constituted unfair, deceptive and unconscionable acts and practices in violation ofO.R.C 1345.02 and 1345.03 and to Substantive Rules and case law.

607. Christ Hospital was fully aware of its actions.

608. Christ Hospital was fully aware that Plaintiff was induced by and relied upon Christ Hospital's representations at the time Christ Hospital was engaged by Plaintiff.

609. Had Plaintiff been aware that Christ Hospital's representations as set forth above were untrue, Plaintiff would not have used the services of Defendants.

610. Christ Hospital, through its agency and employees knowingly committed the unfair, deceptive and/or unconscionable acts and practices described above.

611. Christ Hospital's actions were not the result of any bona fide errors.

612. As a result of Christ Hospital's unfair, deceptive and unconscionable acts and practices, Plaintiff has suffered and continues to suffer damages, which include, but are not limited to the following:

a. Loss of money paid

b. Severe aggravation and inconveniences

c. Under O.R.C. 1345,01 Plaintiff is entitled to:

i. An order requiring Christ Hospital restore to Plaintiff all money received from Plaintiff plus three times actual damages and/or actual/statutory damages for each violation;

ii. All incidental and consequential damages incurred by Plaintiff;

iii. All reasonable attorneys' fees, witness fees, court costs and other fees incurred;

## PRAYER FOR RELIEF

**WHEREFORE,** Plaintiff requests and seeks justice in the form and procedure of a jury, verdict and judgment against Defendants on all claims for the following damages:

I. Past medical bills;

2. Future medical bills;

3. Lost income and benefits;

4. Lost future income and benefits;

5. Loss of ability to earn income;

6. Past pain and suffering;

7. Future pain and suffering;

8. Plaintiff seeks a finding that their injuries are catastrophic under Ohio Rev. Code §2315.18;

9. All incidental costs and expenses incurred as a result of their injuries;

10. The damages to their credit as a result of their injuries;

11. Punitive damages;

12. Costs;

13. Attorneys' fees;

14. Interest;

15. All property loss;

16. All other relief to which they are entitled including O.R.C. 1345.



Based upon 1-16 itemization of damages, the damages sought exceed the minimum jurisdictional amount of this Court and Plaintiff seeks in excess of$25,000.

Respectfully Submitted,

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**JURY DEMAND**

Plaintiff makes a demand for a jury under all claims.

Matthew Hammer (#0092483)
Lindsay L. Boese (0091307)